EXHIBIT F

IN THE COURT OF COMMON PLEAS
OF PHILADELPHIA COUNTY, PENNSYLVANIA
TRIAL DIVISION - CIVIL

IN RE: PELVIC MESH LITIGATION	:	February 2014, No. 829
KATHRYN McGEE and MICHAEL McGEE, Plaintiffs,	:	JULY TERM, 2013
vs.	:	No. 003483
ETHICON WOMEN'S HEALTH AND UROLOGY, A DIVISION OF ETHICON, INC., et al. Defendants.	:	

The deposition of BRUCE ALAN ROSENZWEIG, M.D., taken before Pauline M. Vargo, an Illinois Certified Shorthand Reporter, C.S.R. No. 84-1573, at the law offices of Wexler Wallace, LLP, Suite 3300, 55 West Monroe Street, Chicago, Illinois, on February 4, 2016, at 8:55 a.m.

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I N D E X

Thursday, February 4, 2016

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E X H I B I T S
Continued

E X H I B I T S
Continued

(The witness was duly sworn.)

BRUCE ALAN ROSENZWEIG, M.D.,

called as a witness herein, having been first duly sworn, was examined and testified as follows:

EXAMINATION

BY MR. ROSENBLATT:

Q. Good morning, Dr. Rosenzweig.

A. Good morning, sir.

Q. You have testified a number of times in the pelvic mesh litigation, correct?

A. Correct.

Q. And so today your opinions are focused on TVT Secur, is that correct?

A. Yes.

Q. So, would it be fair to say that we could rely on your previous testimony in your depositions and your trials and we don't have to go back and rehash a lot of those issues?

A. Yes.

Q. There is nothing that you have testified to that you would need to change at this point?

MR. WALDENBERGER: Objection as to being overbroad, but you can answer the question.

BY MR. ROSENBLATT:

Q. I guess what I'm getting at, do you stand by all of your testimony to date?

A. Yes. There might be one or two things that I stated that could be corrected, but none that I specifically recall right now.

Q. But each time you testified you were under oath?

A. Correct.

Q. But nothing you can think of today that you would need to change?

A. Not specifically, no.

Q. When were you first retained to work on the McGee case?

A. In December.

Q. Would that be December of 2015?

A. Yes.

Q. Do you know if it was towards the beginning of the month or the end of the month?

A. Actually, it was right after Thanksgiving, so probably the end of November.

Q. And who retained you?

A. The Kline Specter law firm.

Q. Which specific attorney reached out to

you for your services?

A. Mr. Waldenberger.

Q. And what did Mr. Waldenberger ask you to do on the McGee case?

A. To give opinions about the design, the development and the warnings associated with the TVT Secur.

Q. And how many hours did you spend looking into or formulating your opinions about the design, development and warnings of TVT Secur?

A. Well, I have been working on TVT Secur for longer than that. I had been retained to work on a TVT Secur case, the Rabiola case in Texas, and I had been working on that for over a year. So, much of the information regarding the design, the development and the warnings associated with the TVT Secur I had already been reviewing for that other case.

Q. So when Mr. Waldenberger reached out to you to ask you to formulate your opinions and draft an expert report, how did you go about carrying out that assignment?

A. Well, again, most of, if not all, the information I had already reviewed. I had

depositions set for the Rabiola case that had been continued for approximately six or seven months. So, the information that is contained in my expert report I had already summarized not in report form but in preparation form for depositions that had taken place long before I was contacted about this case.

Q. And so what material did you look at to formulate your opinions?

MR. WALDENBERGER: In general, you mean, with regard to the TVT-S?

MR. ROSENBLATT: With regard to the TVT Secur.

MR. WALDENBERGER: At any point in time?

MR. ROSENBLATT: Yes.

A. Well, as you know, I have been reviewing deposition testimony for four years now, give or take. Much of that deposition testimony overlapped, whether it was for TVT, TVT-O, TVT Abbrevo, and so the majority of the deposition testimony I had already reviewed.

There was a lot of overlap between internal documents, but the specific documents that

I reviewed are outlined in my reliance list.

Q. And you mentioned your reliance list. That would contain internal documents, deposition testimony and literature; is that a fair summarization?

A. Correct.

Q. And it's important to create a reliance list, in your opinion, correct?

A. Well, the reliance list is a list of materials that I've reviewed, and so it summarizes the documents that I've reviewed for my opinions.

Q. And it also summarize the documents that support your opinions, correct?

A. Yes.

Q. And it would be important to include all of the documents in your reliance list that support your opinions about the TVT Secur, correct?

A. Yes. I think I've tried to incorporate all the documents that I've relied on in my opinions.

Q. And in formulating a reliance list to support your opinions for the TVT Secur, you would want to do a fair analysis of, for example, the medical literature?

A. Correct.

Q. And you would want to include on your reliance list medical literature that would be both good and bad for the Secur in order to provide a fair assessment, correct?

A. Well, I've reviewed all the literature regarding TVT Secur or, I would say, the vast majority of the literature regarding the TVT Secur, both literature that would, as you say, supports my opinion and also literature that would -- I don't think the term "contrary to my opinion" but that is more favorable than the vast majority of the literature on TVT Secur.

I think the literature on the TVT Secur -- on the TVT Secur is quite evident that there is a problem with its efficacy and there is a problem with its safety.

Q. Now, you said you reviewed all of the literature on TVT Secur. How many clinical studies are there on TVT Secur?

A. The exact number I cannot give you.

Q. Can you give me a ballpark?

A. I would say I've reviewed, you know, anywhere from 30 to 50 articles on TVT Secur.

Q. Are you aware if there are more than 30 to 50 clinical studies evaluating TVT Secur?

A. There might be more, and again, there are meta-analyses that I've reviewed that would encapsulate the majority of the literature. There are things that I would look at.

Again, there is probably more that I looked at that I briefly glanced over because they might not have been as robust of a study as prospective randomized controlled trials are. So, again, giving a brief number of the studies that I've looked at, I mean, there are probably more than that.

Q. Well, you would agree with me even if you have a meta-analysis or a Cochrane review, you, Dr. Rosenzweig, still find it helpful to go back and review the underlying data that supports those accumulated opinions, correct?

A. Correct.

Q. And did you do that in this case for the TVT Secur?

A. Yes.

Q. Of the 30 to 50 articles on TVT Secur that you reviewed, did you include all of those on

your reliance list?

A. There might be some that might not be on my reliance list, but I try to include everything on my reliance list.

Q. Did you have any type of criteria as far as whether or not you would include or exclude a certain study on TVT Secur?

A. No.

Q. Did you formulate your reliance list, or was that prepared by counsel?

MR. WALDENBERGER: Objection. Don't answer. Under Pennsylvania law communications between expert and lawyer regarding the preparation of a report is privileged, so don't answer.

Q. Your counsel has instructed you not to answer the question. Are you going to answer the question?

A. No.

MR. WALDENBERGER: No, he is not going to answer the question. Good try, though.

Q. How did you obtain the 30 to 50 articles on TVT Secur that you reviewed?

A. And again, that is just a rough

estimation. There could be more. There might be less. Through searches by looking at again meta-analysis and looking at their reference list; and that would be, you know, looking at papers and seeing what they referred to in their papers. That would be a way of getting at the literature that I reviewed.

Q. Did you make any attempt to go back and perform any type of systematic literature review yourself on TVT Secur?

MR. WALDENBERGER: Objection, form, vague.

You can answer if you understand.

A. I don't understand what you are talking about, a systematic review. Again, I looked at --

Q. Strike the question. I will take out the word "systematic."

Dr. Rosenzweig, did you make any attempt to review -- or strike that.

How did you go about ensuring that you reviewed all of the relevant literature on TVT Secur?

A. Well, again, I looked at the studies that had been published. I looked at their

references, looked at the meta-analysis, looked at their references and continued to review studies that were done, did literature searches, and to assure that I had reviewed the depth and the breadth on the subject of TVT Secur.

Q. Did you perform any searches yourself in any type of medical journal database?

A. I have PubMed and access to searches on PubMed, and so yes, I would look at PubMed. Google Scholar is another nice search engine to find scholarly literature, and so if there was a specific topic on TVT Secur that I wanted to look at, those would be the resources that I went to.

Q. And just so I can appreciate your testimony, you did in fact run some PubMed searches on TVT Secur?

A. If there was something that I could not find, then it would be for a specific topic on TVT Secur, yes.

Q. And can you identify those specific topics where you performed a PubMed search on TVT Secur?

A. Not that I specifically recall.

Q. Did you perform a search in PubMed for

TVT Secur to get a better understanding of the volume of clinical studies on TVT Secur?

A. Well, I think the volume of the clinical studies would be reflected in not only the Cochrane analysis but, you know, there are a number of studies, if you will, that were either -- could either be considered like review articles and opinion pieces that might not be as robust as the randomized control trials.

Q. Would it be important for you to look at case studies, case series and observational studies on TVT Secur?

A. Yes. I tried to look at case series, observational studies, retrospective analysis.

Q. You said there are approximately 30 to 50 articles on TVT Secur, just your ballpark range. How many of those 30 to 50 would you consider to be randomized controlled trials as opposed to just a clinical trial?

A. I think there is in the neighborhood of 20 to 30 randomized control trials on the TVT Secur.

Q. Have you reviewed all 20 to 30 RCTs on TVT Secur?

A. I have tried to, yes.

Q. You said you tried to. What efforts have you made other than what you've previously discussed about looking at larger meta-analyses and performing an individual search for an individual topic?

A. Well, that would be one of the topics, would be randomized control trials.

Q. So, when I previously asked you do you recall which topics you specifically searched out, you didn't recall. Is it my understanding that you performed a specific search on RCTs for TVT Secur?

A. Either specifically in that sense or looking at other sources for a list of the randomized control trials for TVT Secur. So, I mean, that was one of the things that I wanted to see, is if I had looked at all or virtually all of the randomized control trials on TVT Secur.

Q. And it would be important to you in formulating your opinions on TVT Secur to look at as many or all of the RCTs and other clinical studies on TVT Secur, correct?

A. Correct.

Q. Because you wouldn't want to just look

at studies that showed bad results or bad cure rates or high complications, but you would want to look at all the studies to get a fair and balanced approach and appreciation of the body of literature on Secur, correct?

A. Correct.

Q. And again, we can stand by and rely on your reliance list for the medical literature that you relied on?

MR. WALDENBERGER: Objection to the form. I believe his prior testimony was that some may not be on there; he just doesn't know that. But with that, you can answer.

A. Again, there would be literature that I have reviewed that I have relied on that might not have been on my reliance list but form this breadth of the opinions that I am giving.

I don't think that -- again, there might be things that are on there that I've reviewed that make up the opinions that I have that might not appear in the reliance list.

Q. But you reviewed your reliance list before you served it or before it was served, correct?

A. Correct.

Q. And have you had a chance to go back and identify if there were any key studies that you could think of that were not included in your reliance list?

A. None that jumped out at me.

Q. And as I'm sure you can appreciate, Doctor, today is our opportunity to ask you about your opinions and what you relied on to formulate those opinions, so what I'm trying to avoid is, you know, before your trial testimony next week getting a supplemental reliance list, because today is my opportunity to ask you about those studies that you relied on.

A. Yes, and I don't think you will be getting a supplemental reliance list.

Q. When you performed your review of the 30 to 50 studies on TVT Secur, what is your understanding of the average objective cured and improved rate for TVT Secur?

MR. WALDENBERGER: Objection to form.

You can answer.

A. I would say that the average objective and subjective cure rate is lower than the

full-length midurethral slings. I would say an average objective cure would be in the range of 70, 75 percent or less. Subjective cure rate is lower than that.

Q. When you say 75 or less, does that mean 70 to 75 would be about average?

A. That would be the high end of the scale. I mean, it all depends on which studies you have looked at. There are studies that show a success rate in the 80s. There are studies that show a success rate in the 50s. I would say that one of the latest meta-analysis by Tommaselli showed about a 75 percent success rate.

Q. And so would you stand by the 75 percent success rate as a fair estimate of the objective cure rate with TVT Secur?

MR. WALDENBERGER: Objection to the form in that you are asking him to summarize and average out all of the complications or success rate for various pieces of literature that have not been identified.

With that being stated, if you can answer that question fairly and accurately, please do so.

A. You know, I think that would be on the high end of the average success rate.

Q. But you cited to a meta-analyses citing 75 objective cure for TVT Secur, correct?

A. Correct.

Q. In your opinion, is that a fair estimate of what the studies that that meta-analyses reviewed showed as a cure rate for TVT Secur?

MR. WALDENBERGER: Objection to form, vague.

You can answer if you understand it.

A. That would be, again, there are a number of studies, the Palomba study, the Oliveira study, that showed a 50 success rate. There are other studies that show a lower rate; Barber study, 50 to 60 percent success rate. So, I think 75 percent success rate is a high average.

There is the Tommaselli's older studies that have showed and 80, 85 percent success rate. But even in the last Cochrane analysis that was done, they showed a success rate that was lower than full-length midurethral slings.

Q. What is your understanding of the success rate for full-length midurethral slings?

A. In the short term, around 90 percent success rate.

Q. And what is your definition of short term?

A. In the one- to two-year studies.

Q. What about long-term?

A. Well, again, it all depends on if the parameters that we are using, if you look at the urinary incontinence treatment at work, when their studies come out they use a composite index of stress test, of pad test, symptoms, and other treatment for urinary incontinence.

So, if you look at Richter's study, her one-year success rate was around 55 percent for midurethral slings. The Barber study was about 60 percent using a composite index.

If you just look at cough test or if you just look at pad test, you are going to have -- as your objective measure, you are going to have a higher success rate.

Q. But, Doctor, you would agree with me based on the Urinary Incontinence Treatment Network studies that you were citing to, using those same objective criteria, you would admit or agree with

me that the success rates for both the Burch colposuspension and the autologous fascial sling were significantly lower than what is typically cited as the average cure rate, correct?

MR. WALDENBERGER: Are you talking about mini-slings or full-length slings?

MR. ROSENBLATT: Do you understand the question?

MR. WALDENBERGER: I'm asking you because that may be outside the scope of the deposition. So, I have to make sure that I can either object, let him answer or instruct him not to answer, so I need to --

MR. ROSENBLATT: I'm not asking about either of those. I'm asking about the Burch and the autologous sling.

MR. WALDENBERGER: You can answer.

A. In one to two years, not significant. Lower than that, the longer term, you know, showed a lower success rate.

Q. And if you were citing the success rate for either the Burch procedure or the autologous sling procedure, would you cite the Urinary Incontinence Treatment Network's objective cure

rate?

A. Well, again, that is a very -- what's the word --

Q. Stringent?

A. -- stringent, thank you very much, criteria for measuring success. And so if you are going to use the stringent criteria, you are going to have a lower success rate from any incontinence treatment.

Q. So, if we take the urinary incontinence any treatment studies aside, because you referred to that as a cite to objective cure rates for full-length slings, so if we take those studies aside, what is your appreciation --

A. You are the one that brought up those studies, and I was just commenting on that.

Q. Right. Well, let's back up for a second. I asked you what your appreciation was for the average cure rate for full-length slings, and you cited to the Tomasz study.

A. No. I was citing to Richter's 2011 study and Barber's 2009 or 2010 study.

MR. WALDENBERGER: Paul, how is this within the scope of the TVT-S report?

MR. ROSENBLATT: Because he said that the cure rate for Secur is lower than the full-length midurethral sling, and so I'm trying to figure out is it 5 percent lower, 10 percent lower.

MR. WALDENBERGER: Fair enough.

MR. ROSENBLATT: Now you know where I'm going, Doctor.

MR. WALDENBERGER: That was the point of my objecting, so go for it.

BY MR. ROSENBLATT:

Q. How much lower on average is the objective cure rate for TVT Secur compared to full-length midurethral slings?

A. If you look at some of the head-to-head studies, it can be anywhere from, you know, 15 to 40 percent lower for full-length midurethral slings. If we looked at the Hinoul paper, it showed a lower success rate. The Hota paper showed a significantly lower success rate from midurethral slings.

Q. And Doctor, I appreciate you citing a few specific examples, and while you are doing that, you would agree with me that there are

studies that showed a much higher cure rate for TVT Secur, correct?

A. Yes, but still there are very few studies that showed an equivalent success rate for --

Q. But the answer to my question was yes?

A. Yes.

Q. And you would agree with me that there are studies that show an objective cure rate for TVT Secur in the 90 percentage range, correct?

A. Correct.

Q. And there are some studies that report an even higher objective cure rate for TVT Secur, correct?

A. Correct.

Q. So, when you are telling me that there is one study that shows it's X percent and another study showing Y percent, what I'm trying to figure out is how you are going about citing those specific studies for your appreciation of the average cure rate.

MR. WALDENBERGER: Objection, form, vague.

You can answer if you understand it.

A. Again, when the literature is looked at as in a systematic review like the Cochrane analysis, the Tommaselli analysis and others, including the FDA analysis, when you look at TVT Secur compared to full-length midurethral slings, the success rate is lower and significantly lower.

Q. When you say significantly, that's statistical significance?

A. Yes.

Q. Now, you cited -- I'm not going to be able to list all of them, but, for example, you cited Hota 2012, you cited Hinoul. Why did you call out those specific studies when I asked you about objective cure rates?

A. Those were well-designed prospective randomized control trials.

Q. And do you have any understanding as to whether or not Ethicon had any involvement in those two studies?

A. If we can pull out the studies specifically, I think there would be -- it would allow me to talk specifically about the answer to that question, whether or not they were --

Q. And I'm not asking did they provide a

grant or did they provide the product. Do you know if they had any involvement in either of those studies?

MR. WALDENBERGER: I think he told you he needs to see the article in order to answer that question.

Q. So is your answer you don't know without looking at the study?

A. Well, I know that Dr. Hinoul, I'm not sure whether at that point was one of the medical directors when the TVT Secur, TVT-O study was done, but either at that point or shortly thereafter became a medical director.

Several of the authors both on the Hota study and on the Hinoul study are key opinion leaders for Ethicon. So, it's difficult to answer without looking to see specifically what they stated in the conflict of interest section about either their involvement with industry or the level of industry's involvement in the study.

Q. Did you consider potential bias of those two studies before you stood by them to cite those studies for the objective cure rates for TVT Secur?

MR. WALDENBERGER: Objection to the

form of the question, mischaracterizes them, but you can answer that.

A. I looked at that for every study that I look at.

Q. And that would be important for you to have an understanding as to whether or not, for example, a study was an investigator-initiated study that had some funding provided by Ethicon, correct?

A. Yes, and I look at that to answer your specific question. It would be important to have the specific article in front of me to --

Q. I'm just asking in general terms.

MR. WALDENBERGER: Let him finish his answer.

A. In general terms, yes, but to answer a specific question, it would be important to have the specific article in front of me to be able to say this is what that specific article, you know, laid out as the conflicts and what, you know, involvement industry had either as an investigator-initiated study or a sponsor study or a grant study or just key opinion leader studies.

Q. Just speaking in general terms, you

wouldn't write off or discount the results of an RCT evaluating TVT Secur simply because there was some connection, whether it was to Ethicon, whether it was authored by a key opinion leader or a grant was provided for the study or any type of financial connection, correct?

MR. WALDENBERGER: Objection to the form. I kind of lost sight of the question. Could you read that back to me, please?

And I'm not being critical, Paul. I just lost it.

MR. ROSENBLATT: No worries.

THE REPORTER: "Just speaking in general terms, you wouldn't write off or discount the results of an RCT evaluating TVT Secur simply because there was some connection, whether it was to Ethicon, whether it was authored by a key opinion leader or a grant was provided for the study or any type of financial connection, correct?"

MR. WALDENBERGER: Objection to form. You can answer.

BY THE WITNESS:

A. Again, without looking at the

methodology of an individual study to see if the methodology was sound, to see if they had a robust patient population to provide a power analysis that would allow you to draw conclusions from the study, in general the answer would be no, but we would have to look at the specific paper to see whether or not bias might have influenced the study because of parameters such as the ones I talked about.

BY MR. ROSENBLATT:

Q. And when you were reviewing the 30 to 50 articles on TVT Secur, did you, yourself, perform an analysis as to the potential bias for each of those studies?

A. I think we have discussed the literature enough in past depositions that I have looked at all of the aspects of a study in evaluating it, and that would be one of the aspects that I would look at.

Q. But it would be fair to say, if we are looking solely at a disclosure that indicated a study was funded by Ethicon, you would not based on that one factor discount the results of the study, correct?

A. Based on that one factor, no.

Q. Because there would just be a potential for bias, correct?

A. Correct.

Q. How do you distinguish between a potential for bias and actual bias when you are reviewing medical literature?

A. Again, you have to look at all the aspects of the study, what the hypothesis is that the study is trying to answer, what the methodology was in going about answering that question, whether they had stringent methodology, whether they had a robust enough study design to answer their question, whether they had a significant enough patient population; and then you look at what conclusions they drew based on their analysis to see if the conclusions that they are drawing is supported by the facts that are in the study to determine if they are, you know, overselling their conclusions based on what they found in the study; and then I would be a little bit more concerned about bias.

Q. So, it would be fair to say that a potential conflict of interest is just one factor that you would look at for potential bias?

A. When I review the literature, whether it's in this litigation or whether it is in my practice in determining how I'm going to treat my patients, yes, that is something that I take into consideration when I review any piece of literature.

Q. Now, Doctor, as I appreciate your earlier testimony from this morning, you cited the Tommaselli study for the proposition that the average objective cure rate for TVT Secur is 75 percent with the understanding that there are some studies that show a lower rate and some studies that show a higher rate; is that accurate?

A. Correct.

Q. Now what I want to ask you, Doctor, is taking that same approach, what is your understanding of the average mesh exposure rate for TVT Secur?

A. The Tommaselli meta-analysis showed there was an erosion rate from their review of the literature of 15 percent. I would say that that is a -- from looking at the literature, that that is a accurate representation of what was shown in the literature.

Q. Just so I'm clear, your understanding is that the average mesh exposure rate for TVT Secur is 15 percent?

A. That's what Tommaselli's most recent meta-analysis showed.

Q. But is that a number that you stand behind?

A. That is what Dr. Tommaselli published in his meta-analysis. There is studies that show a erosion rate of 19 percent. There are other studies that show an erosion rate of around 10 percent, 8 to 9 percent. I think that between 10 and 15 percent would be the average erosion rate for a TVT Secur.

Q. You said there are some studies that show an erosion rate of 19 percent. How many studies evaluating TVT Secur show a mesh exposure rate of 19 percent or higher?

A. The 19 percent was Hota's randomized control trial from 2012 that we talked about earlier.

Q. So is the answer one study?

A. I don't recall all of the smaller studies that -- or case series that might have been

published on that. That is the highest one that I saw in a randomized control trial.

Q. So no others that you can think of right now that would show a mesh exposure rate of 19 percent or higher other than the Hota study?

MR. WALDENBERGER: Objection, asked and answered. You can answer it again.

A. Not that I specifically recall.

Q. Do you know how many studies evaluating the TVT Secur showed a mesh exposure rate of less than 5 percent?

A. There are studies that showed an exposure rate of less than 5 percent.

Q. My specific question, though, was, do you know how many studies showed a mesh exposure rate evaluating TVT Secur less than 5 percent?

A. The exact number?

Q. I will take a ballpark range.

A. I wouldn't want to speculate on a ballpark range.

Q. So as you are sitting here today, you cannot tell me or provide me your best guess as an expert offering opinions on the safety and efficacy of the TVT Secur how many studies show a mesh

exposure rate of less than 5 percent?

MR. WALDENBERGER: Objection to the form. He is not here to guess. You can answer.

A. The exact number I would not want to speculate on, I mean, just like I would not want to speculate on the number that showed an erosion rate of over 5 percent. I mean, to look at the specific, you know, number of papers that would give you that number, as I said, there are papers that show an erosion rate of less than 5 percent.

Q. Can you cite any of them today?

A. There is a Tommaselli study. There is the Anders Hamer study. So, there are studies that show an erosion rate less than, you know, 5 percent. Neuman's 2011 paper showed a lower erosion rate than his 2008 paper.

Q. So, how do those lower exposure rates factor into your consideration when you, Dr. Rosenzweig, are formulating what you believe to be the average mesh exposure rate for TVT Secur?

A. Again, you would look at all the papers. You would look at the analysis that have been done such as the Tommaselli systematic review to come up

with a average that you were asking me about earlier.

Q. And that average in the Tommaselli article that you are citing, was that specifically 15 percent mesh exposure for TVT Secur, or did it also include other slings?

A. Just TVT Secur.

Q. And so that is the study that you are standing by as far as your estimate of the mesh exposure rate for TVT Secur?

A. That is the latest systematic review that I could find or the most contemporary systematic review that I could find.

Q. What is your understanding of the average rate of de novo dyspareunia associated with the TVT Secur?

A. In the 2011 Neuman study, he quoted a rate of 8 percent. The Abdelwahab paper around the same time showed a similar dyspareunia rate. In the Anders Hamer paper they discussed pain and dyspareunia and discharge. They had a 13 percent dyspareunia rate. So, I would say that the de novo dyspareunia rate is probably around 8 to 10 percent for the TVT Secur.

Q. And what is your understanding of the -- strike that.

You mentioned 8 to 10 percent de novo dyspareunia rate for TVT Secur, and what I want to know is how far postoperatively does that include?

A. Well, it's difficult to get an accurate number because, again, if the study does not describe pain and dyspareunia, we don't know whether that means that there was no pain or dyspareunia or that the question was just not asked.

Many of the studies include various surveys, if you will, like the IIQ and the pelvic floor symptom questionnaire or pelvic floor sexual dysfunction, which includes questions on dyspareunia but the exact number is not given. And so while they might show that there is a change in the pre-op and the post-op survey results, it's not reflected in the individual parameters that are there.

So, unless a paper specifically talks about dyspareunia, it's difficult to know whether or not the question was even answered, whether or not the patient volunteered those questions. So,

it's difficult by the study design to know what that answer is.

Q. And you would agree that dyspareunia in general is somewhat complicated to study in clinical studies, correct?

A. It is difficult to study if the question is not asked.

Q. But you agree that it is difficult to study for a number of reasons and some of those would include whether or not you evaluate preoperative or preexisting dyspareunia, correct?

A. Well, your question was de novo dyspareunia, which would mean that there was no preexisting dyspareunia. I think a better question would have been you have to evaluate patients who are sexually active, because if they are not having sexual intercourse, it is very difficult to have pain with sexual intercourse.

So, the better question is what is the number of patients that are sexually active post-op to be able to determine whether or not they developed pain, and that's --

Q. Could you answer your own question for me?

A. And that's why I said it's very difficult because -- because of the design of the -- you know, you have to look at the study design and if they actually asked those questions. The studies that I described actually asked those questions.

Q. Again, are you aware of any studies that show a rate of de novo dyspareunia higher than 8 to 10 percent with the TVT Secur?

A. Sitting here today, those, that I cannot recall specifically.

Q. So the 8 to 10 percent de novo dyspareunia rate for the TVT Secur is on the highest end of the spectrum, correct?

A. Correct.

Q. You are aware that there are clinical studies evaluating TVT Secur that show a significantly lower dyspareunia rate, correct?

A. If you have those papers, we can discuss them in the individual. In general, there are few papers that describe dyspareunia rates that are lower than that for TVT Secur.

Q. And we may look at some studies, but I'm just asking your -- just your overall impression,

are you aware of whether or not those studies exist?

A. And I gave you my overall impression.

Q. I don't know if I had a clean answer to whether or not you are aware that --

MR. WALDENBERGER: Why don't you fire the question again, give it another shot.

MR. ROSENBLATT: Sure. Let me reload here.

BY MR. ROSENBLATT:

Q. You would agree that there are clinical studies evaluating TVT Secur that show a significantly lower dyspareunia rate than 8 to 10 percent, correct?

MR. WALDENBERGER: Objection to form, asked and answered. You can answer it again.

A. There are a small number of studies that show that, yes.

Q. And one component that can make studying dyspareunia in a clinical trial difficult is determining whether or not dyspareunia was caused by a concomitant procedure as opposed to the TVT Secur, correct?

A. If concomitant procedures were part of

the study design, then there could be confounding variables from that unless the investigator was able to determine that the TVT Secur, as in the Neuman study did, was the cause of the dyspareunia.

Q. But you would agree that it is important when evaluating de novo dyspareunia to look at other factors such as whether or not the patient underwent a concomitant procedure?

A. Correct.

Q. And some of those concomitant procedures can commonly include a vaginal hysterectomy or a surgical procedure to correct a condition called pelvic organ prolapse, correct?

A. Those procedures cannot uncommonly be performed with a incontinence operation.

Q. And when looking at a study that cites a dyspareunia rate, it would be important for you to have an appreciation of whether or not those patients underwent concomitant procedures, correct?

A. Correct.

Q. Because concomitant procedures such as a hysterectomy or a procedure to correct pelvic organ prolapse in themselves have a risk of de novo dyspareunia?

A. Well, specifically the way the concomitant procedures are being done could increase the risk of dyspareunia, such as if you are doing a vaginal hysterectomy and you attach the pedicle to the vaginal cuff, that could increase your risk of dyspareunia because the pedicles are innervated, and we know from gynecology that the ovarian pedicles when pulled on or manipulated can cause a significant degree of pain. There are a lot of women that have ovarian pain specifically from an entity called ovarian torsion; and when you twist the ovarian pedicle, it can become very uncomfortable for a patient.

We've discussed that levator plications with posterior repair significantly increases the risk of dyspareunia after a posterior compare up in the range of 20 percent compared to the newer data on posterior repairs that show only about a 4 percent or less risk of dyspareunia if no levator plication is done.

So, in order to answer that question, yes, we have to know exactly how the surgical procedures, concomitant surgical procedures were being done to be able to evaluate whether or not

that could be a compounding factor in whether or not the patient developed postoperative dyspareunia.

Q. And if a patient in a clinical study underwent a TVT Secur as well as a concomitant vaginal hysterectomy, how would you do the differential diagnosis to determine whether the pain or dyspareunia was attributable to the Secur or the hysterectomy?

A. Well, again, you would have to look at the methodology to determine how they did the pelvic organ prolapse repair.

Anterior colporrhaphies are very unlikely to cause dyspareunia. We know that from several of the studies. Posterior repairs have been associated with dyspareunia if the levator plication was done.

So, if it's characteristically described in the paper that our posterior repairs were done with levator plications, then you would rule in the posterior repair as a potential cause.

If the posterior repair is not done with a levator plication, the current studies are showing that there is a much lower rate of

dyspareunia.

If a vaginal hysterectomy is done where the pedicles are attached to the vaginal vault, that could be a significant source of dyspareunia.

The description of what the dyspareunia is, where the location is, if palpating the sling causes pain, if you are having banding or palpability of the sling during the exam, which was described in other papers that described dyspareunia and pain associated with slings, then you could rule -- say that it is more likely that the dyspareunia is caused by the sling.

If there is no other concomitant procedure, obviously the dyspareunia would be due to the sling itself.

Q. Now, you mentioned the anatomical location of where the pain would be with the TVT Secur. Is it your understanding that the pain or the postoperative pain and dyspareunia commonly associated with the TVT Secur would be kind of the banding underneath where the Secur sling sits?

A. Not necessarily. We know that, you know, the pelvis isn't an isolated structure. We know that there can be some -- because of the

chronic inflammation, the chronic foreign body reaction, that this can impact the levator muscles, which are just lateral to where the TVT Secur fleece is supposed to lay, and that could then increase levator spasm and levator pain, which can be associated with dyspareunia.

Q. What is your appreciation of the rate of dyspareunia caused by TVT Secur attributable to levator spasms?

A. That specific description I have not seen in the studies that I've reviewed.

Q. And so the studies that you have reviewed, where do they typically describe the pain or dyspareunia with the TVT Secur?

A. Well, in the Neuman paper specifically, he talked about the stiffness or rigidity of the TVT Secur as causing dyspareunia. The Hota paper felt that it was sharp edges associated with the TVT Secur that would lead to pain. So, specifically they were describing the characteristic defects of the TVT Secur in those papers that were related to the consequence, which would be dyspareunia.

Q. But that would be where the sling is, if

I understand what you are saying?

A. Well, they were describing the characteristics of the sling that would lead to dyspareunia, and where the -- most patients when -- now we are kind of getting away from studies and clinical practice.

Most patients just know that it hurts when they are having intercourse. Some patients try to describe an anatomic location where they say most of the pain is, but most patients, if they -- so, if someone said like I have pain on introduction, many times what that is is just spasm of the muscles in anticipation of the pain with intercourse. If someone says that it's only when you hit a certain location in my vagina, then that would be a indication of where the source, if you will.

But the vast majority of patients that I see in my clinical practice say it hurts. They try to give a very vague description of where the pain is, but it's very difficult to truly say what specific anatomic location the pain is being generated by. They just know it hurts when they are having intercourse.

Q. So if I understand your testimony, you referred to the Neuman paper and how they theorized that the stiffness of the mesh caused dyspareunia?

A. Correct.

Q. Is it your understanding that based on that theory that it would be the pain would be where the mesh is or elsewhere?

A. I just described for you my clinical experience dealing with patients that have dyspareunia and particularly dyspareunia from midurethral slings or from single-incision slings; and they are describing the defect Dr. Neuman and Hota were describing, the defect of the sling that caused dyspareunia.

That doesn't necessarily mean that that is the only place where the patient is going to say that their pain is coming from when they are having intercourse.

Q. Now, when you have pain or dyspareunia from a native tissue repair, do you refer to that as any type of defect causing that pain or dyspareunia?

A. Again, as we talked about, a levator plication with a native tissue repair would be

an -- would be the causative factor, because what you are doing is you are creating a very firm shelf of muscle that when you are having intercourse is more likely to spasm or to have abnormal scarring in muscle that shouldn't be there.

So levator plications, we used to think that doing a levator plication would improve the anatomical results. It made the posterior repair look better but created a significant degree of dyspareunia.

Q. And with procedures such as a hysterectomy or a pelvic organ prolapse procedure, those come with them the risk of vaginal scarring and shortening, correct?

A. Scarring would be along the incision line because that is where the tissue is healing. Shortening would be caused by excessive removal of vaginal tissue. And another thing that has evolved is the concept that you need to take out a significant amount of vagina to create a scaffold for the prolapse.

Now, the native tissue repair is that scaffold is from bringing endopelvic fascia together and you do not take out vagina because the

vagina is not going to act as a scaffold.

Q. But the old way of doing it wasn't necessarily outside the standard of care, correct?

MR. WALDENBERGER: Objection, outside the -- hold on a second. How is that within the scope of this deposition?

MR. ROSENBLATT: I'm just trying to get his understanding as to whether or not a change in the surgical procedure makes that then become outside the standard of care.

MR. WALDENBERGER: Right. How is that within the scope of a TVT-S deposition?

MR. ROSENBLATT: I think it is relevant to his reasoning and understanding, and I don't think it has been previously asked.

MR. WALDENBERGER: It doesn't mean it's within the scope. I will let you go with that one, but --

MR. ROSENBLATT: I mean, you can object, but --

MR. WALDENBERGER: Objection is noted. I'm not going to instruct him not to answer. Go ahead.

BY THE WITNESS:

A. I can't go back and say, you know, 20 years ago that it would be outside the standard of care to do the kind of repairs we used to do.

BY MR. ROSENBLATT:

Q. Would you agree with me that when TVT Secur was on the market it was within the standard of care for treating women with stress urinary incontinence?

MR. WALDENBERGER: During what period? The entire time it was on the market?

MR. ROSENBLATT: I will just let him -- are you objecting?

MR. WALDENBERGER: I am objecting because I think your question is vague.

MR. ROSENBLATT: I will ask it open-ended and then I will come back and narrow it down if he needs me to.

MR. WALDENBERGER: Did you need that narrowed down?

THE WITNESS: It would be important to narrow it down.

MR. WALDENBERGER: I instruct you not to answer until he narrows it down.

BY MR. ROSENBLATT:

Q. Doctor, at the time TVT Secur was launched onto the market in 2006, what is your understanding of whether or not TVT Secur was within the standard of care for treating stress urinary incontinence?

MR. WALDENBERGER: Objection to the form. You can answer.

A. Well, obviously doctors back in 2006 when the TVT Secur was launched onto the market -- and I think we can agree that was around September of 2006.

Q. If that's your understanding.

A. The doctors that were performing it did not have all the information that the manufacturer did about the risks associated with the device. Those risks were not communicated to doctors, as I have stated in my report. All the risks that were associated with the device which was known to the manufacturer were not communicated to doctors, and the risks of not only the defects associated with the device but the difficulties in doing the procedure which were not communicated to doctors were not communicated to doctors.

So, I cannot fault the doctor for having placed the TVT Secur in 2006 because they didn't have all the information to make a reasonable decision about whether or not they should be placing this in a patient.

Q. And I understand all of your opinions about the defect and the failure to warn, and we are going to go through those in more detail, but those issues aside, you would agree that TVT Secur was not outside the standard of care for treating stress urinary incontinence?

MR. WALDENBERGER: Objection, asked and answered. I will let him answer one more time.

A. As I say, I cannot hold the doctor at fault for placing a TVT Secur in 2006 because the doctor did not have all the information that the manufacturer had about all the risks associated with it.

Having known all the risks that are associated with it, then it would, as it is today, would be unreasonable for a doctor to place a TVT Secur.

Q. If a doctor acknowledged that he or she

was aware of all of the risks, would you still place any fault on them for implanting a TVT Secur while it was on the market?

MR. WALDENBERGER: I object to the form of the question because you are not identifying what the risks are or what the risks are from. So, in that regard I ask you to rephrase the question because I don't think it is capable of being answered as asked.

MR. ROSENBLATT: I will rephrase.

BY MR. ROSENBLATT:

Q. If a surgeon knew of all the risks that you have listed in your expert report and still decided that TVT Secur was an appropriate option for a patient that they were treating, would you fault them for using TVT Secur?

MR. WALDENBERGER: Objection to the form. You can answer.

A. As I say, I do not fault the doctors.

Q. So you would agree with me that there are some doctors who felt like TVT Secur was an appropriate option for patients with stress urinary incontinence?

MR. WALDENBERGER: Objection, calls

for speculation. You can answer.

A. As I state, I do not fault the doctors.

Q. But my question was slightly different, and I appreciate your answer, but you would agree that when the TVT Secur was on the market there were surgeons who felt as though TVT Secur was an appropriate option for treating women with stress urinary incontinence?

MR. WALDENBERGER: Objection, calls for speculation. You can answer.

A. And as I've stated, I do not fault the doctors.

Q. But I don't think you have still answered my question as far as you would agree that there were surgeons who felt that it was an appropriate treatment option for treating stress urinary incontinence?

MR. WALDENBERGER: In my view he has answered your question, so I'm going to instruct him not to answer that any longer.

MR. ROSENBLATT: And as I appreciate it, he has answered the question that he doesn't fault the doctors, but I'm asking a different question, which is you would agree

that there were surgeons who felt as though the TVT Secur was appropriate for treating some women with stress urinary incontinence.

MR. WALDENBERGER: Paul, we both understand your question, and in my view it not only is speculative, but aside from being improper because it is speculative, he has answered it. So, I'm going to instruct him not to answer it because I think he has already answered that I think three times. So if you could move on to your next question, we would appreciate it.

BY MR. ROSENBLATT:

Q. Are you unable to answer the question because you are not sure what surgeons thought at the time?

MR. WALDENBERGER: I'm not permitting him to answer it because he has already answered it and it is speculative, because you are asking him to go into the minds of other people, which he can't do, but he did the best he could do by answering it the way that he did, which is his answer.

MR. ROSENBLATT: I think you can make

your objection, and I appreciate you elaborating, but I think he can still answer the question.

MR. WALDENBERGER: Not when I tell him not to, which is what I'm doing, because he has already answered.

MR. ROSENBLATT: On the basis of your expert speculating?

MR. WALDENBERGER: On the basis that he has answered it twice.

MR. ROSENBLATT: Well, I'm asking a different question now.

MR. WALDENBERGER: I haven't heard a different question but I'm happy to listen to that. Let's take it from there. What's the new question?

BY MR. ROSENBLATT:

Q. My previous questions were you would agree that TVT Secur was within the standard of care, and you said you would not fault the doctors, correct?

A. Correct.

MR. WALDENBERGER: Objection, asked and answered. He has already answered that

question, so please move on to the next question.

BY MR. ROSENBLATT:

Q. I understand. I'm providing you the previous question. Now my new question is -- my new question is you would agree --

MR. WALDENBERGER: I'm breathless with anticipation.

Q. -- that there were surgeons who felt as though TVT Secur was an appropriate treatment option for women with stress urinary incontinence?

MR. WALDENBERGER: Paul, you have asked it three times.

MR. ROSENBLATT: But you haven't let him answer all three times.

MR. WALDENBERGER: Yes, I have let him answer three times,and when you try a fourth and a fifth time, that's when I shut him down. He is not answering the question. He has answered it.

MR. ROSENBLATT: But he hasn't. I'm going to insist that he answer the question.

MR. WALDENBERGER: And I'm going to insist that he not answer it, so why don't we

just move on to the next one.

BY MR. ROSENBLATT:

Q. Are you refusing to answer the question?

MR. WALDENBERGER: He is following my instruction not to answer.

Q. Are you refusing to answer the question?

A. I'm following the instruction of counsel.

MR. WALDENBERGER: Right.

Q. Doctor, did you review Ms. McGee's deposition?

A. No.

Q. Have you reviewed any depositions of Ms. McGee's family or friends?

A. No.

Q. Have you reviewed any deposition of Ms. McGee's treating physicians?

A. No.

Q. Is it fair to say that you have not reviewed any deposition testimony specific to the McGee case?

A. Correct.

Q. Is it also fair to say that you have not reviewed any of Ms. McGee's medical records?

A. Correct.

Q. So, it would then be fair to say that you are not offering any case-specific opinions in the McGee case, correct?

A. Correct.

Q. And so you obviously didn't perform a physical exam on Ms. McGee?

A. Correct.

Q. And you have never spoken to Ms. McGee?

A. Correct.

MR. WALDENBERGER: Paul, we have been going a little more than an hour, and I have drank too much water. Can we take a five-minute break for the restroom?

MR. ROSENBLATT: We can, and when you come back, that would be great if he could answer that question.

MR. WALDENBERGER: I'm not going to change my mind. We are going to go off the record.

(Recess taken, 10:14 - 10:26 a.m.)

MR. LUNDQUIST: As discussed with counsel on the break, this is Will Lundquist, I'm appearing on behalf of the MDL.

Mr. Aylstock cross-noticed this deposition on behalf of the MDL as a de bene deposition. From what I understand, to clarify, I don't think there is any doubt that this is a discovery deposition for Dr. Rosenzweig on the TVT Secur, and I'm appearing on behalf of the MDL at this discovery deposition for Dr. Rosenzweig on the Secur.

MR. ROSENBLATT: Thanks, Will.

BY MR. ROSENBLATT:

Q. Doctor, we are just coming back from a break. I notice you have some binders sitting in front of you. Do you mind telling me what those are?

A. Those are the citations that are in my report numbered from 1 through 91.

Q. And when you say citations in your report, is that referring to either the documents or the literature that are specifically referenced in the body of your report?

A. Yes, in the footnotes of the report.

Q. So, those two binders would not include all of the studies that are on your reliance list, correct?

A. No.

MR. ROSENBLATT: If I could, Madam Court Reporter, mark each of those binders as Exhibit 1 and Exhibit 2.

(Rosenzweig Exhibits 1 and 2 were marked for identification as of 2/4/16.)

BY MR. ROSENBLATT:

Q. Dr. Rosenzweig, we have just marked the binders that we brought with you as Exhibits 1 and 2. Did you bring anything else with you?

A. A copy of my report and the notice of deposition.

MR. WALDENBERGER: Just so you know, Paul, we are not producing these binders. They are his binders for purposes of what his materials are, but the documents are what they are. You know what they are based on the footnotes, but I just want to let you know we are not giving them to you guys now. They are Bruce's binders.

MR. ROSENBLATT: We are going to want a copy of everything.

MR. WALDENBERGER: I will gladly have

copies made for you.

MR. ROSENBLATT: Is there any highlighting in there?

THE WITNESS: No.

MR. WALDENBERGER: You would have to answer that.

THE WITNESS: No.

MR. ROSENBLATT: During the next break I just want to flip through it, and if you could give me a flash drive then, problem solved.

MR. WALDENBERGER: Even better, yes, we will do that, and I will get that in the works for you right now. We won't have it for you today, but I will get it to you when it gets prepared.

BY MR. ROSENBLATT:

Q. Is there any reason you didn't bring all of the literature that's on your reliance list?

A. It would be quite a voluminous task.

Q. Doctor, I want to go back to something. I'm going to try to phrase it to avoid your counsel from objecting.

MR. WALDENBERGER: Good luck.

Q. You would agree with me that TVT Secur was a recognized treatment option for stress urinary incontinence as early as 2006, correct?

MR. WALDENBERGER: What's that question again?

THE WITNESS: Recognized treatment option.

MR. WALDENBERGER: I will let him answer that.

A. Correct.

MR. WALDENBERGER: Well done. I did not object.

BY MR. ROSENBLATT:

Q. Doctor, you may disagree with whether or not TVT Secur was an appropriate option, but you would acknowledge that there were some doctors who used TVT Secur to treat stress urinary incontinence?

A. There were some doctors that used TVT Secur to treat stress urinary incontinence.

Q. And as you said earlier, you don't fault them for that?

A. Correct.

Q. And you would agree that TVT Secur was

an appropriate option for some patients to treat stress urinary incontinence, correct?

MR. WALDENBERGER: Objection to the form. You can answer.

A. Do I feel it was an appropriate option?

Q. We will start with that.

A. No.

Q. But you would agree that there were some doctors who did feel that it was an appropriate option?

A. You asked that question. I answered that question yes.

Q. I also want to go back to something. When we were talking about the objective cure rates for TVT Secur, I believe you gave me the figure 75 percent based on the Tommaselli study. What is your understanding of the subjective cure rate for TVT Secur?

A. It is less than the 75 percent.

Q. How much less?

A. Again, I would say in the range of a high end would be 70 percent.

Q. And what are you basing that on?

A. Review of the literature, review of the

systematic reviews.

Q. And you would acknowledge that there are studies evaluating TVT Secur that report a much higher subjective cure rate than 70 percent, correct?

A. Correct.

Q. How do those studies factor into your analysis of 70 percent?

A. I reviewed again all the studies that look at more favorable results. There are also studies that show that there was a 30 to 50 percent subjective cure rate.

Q. Now, when you said you reviewed all the studies, I just want to make something clear. You are referring to the studies listed in your reliance list, correct?

MR. WALDENBERGER: Objection, form, asked and answered. I don't believe he said that, but he can answer that question and explain it again.

A. Again, I reviewed a number of studies on TVT Secur. All of them may or may not be on my reliance list.

Q. But if they were important, you would

put them on your reliance list?

MR. WALDENBERGER: Objection, asked and answered. Paul, I thought we had gone over this, but I'm happy to have him answer it again. Go for it.

A. There might be some important studies that might not have made it on to my reliance list.

Q. Now, Doctor, I know you have testified to some of this in the past, so I'm going to try to breeze through this portion very quickly, and where I'm trying to get is very specific to TVT Secur, but just to set up my questions, I do want to ask you some that you have already answered.

I believe you told us you have removed or explanted approximately 200 slings?

A. Correct.

Q. And when we say removed or excise, I believe you testified or you told us that would include trying to remove as much of the mesh as possible?

A. Correct.

Q. That would also include a trimming a small mesh exposure?

A. Correct.

Q. That would also include a simple take-down procedure?

A. You mean a release procedure?

Q. Yes.

A. Yes.

Q. For a release procedure you are essentially just pulling the mesh down with maybe a nerve hook and cutting the mesh so you are not cutting into the urethra, correct?

A. If that's possible. Sometimes we have to transect it in situ without the ability to get an instrument such as a nerve hook or a hemostat or a Lahey or a very narrow right angle behind it, but because of the degree of scarification, scar plate formation, the degree of fibrosis, chronic foreign body reaction, to be able to safely separate it so that we would just separate it in situ.

Q. One of the benefits with at least the TVT mesh is that it's blue, correct?

A. That was one of the things that was cited back in 2004, if I remember correctly, when it was converted from a clear to a blue color. It would help with implantation but would also help with removal.

Q. Did you find that to be beneficial when you were removing?

A. Sometimes it's difficult to tell whether the blue is from a vein or a blood vessel or the blue is from the mesh. I have, unfortunately, transected a number of blood vessels thinking that it was the mesh only to find out that it was a blood vessel. So, sometimes it made it easier, sometimes it increased the degree of complications of the procedure.

Q. I believe you told us of those 200 removal or excision, or I use the word take-down -- what did you use?

A. Release.

Q. I will start over.

So, of those 200 removal, excision or release procedures that you performed on slings, I believe you told us about 40 to 50 of those procedures would have been Ethicon's TVT meshes?

A. That would be a rough estimate. It is probably a little bit higher now since I have done a few more since the last discussion where I gave a number like that.

Q. How many TVT meshes have you removed in

2016?

A. Two or three. I think I just did one last week.

Q. So that number may be 40 to 53 now, approximately?

A. Yes.

Q. And of those, I will say, 40 to 53 Ethicon meshes that you have removed or excised or released, how many of those were laser-cut TVT slings?

A. That I can't tell you because I don't always get the product, a UPIN number I think is what it's called, or identification number; and even when I have looked on the product identification sticker, I haven't seen where it specifically states whether it's mechanical cut or laser cut.

Q. But you know if there is an "L," that means it is laser cut, on the product sticker, right?

A. Yes.

Q. How many of those 40 to 53 Ethicon TVT slings that you have removed were TVT Secur?

A. Less than five, and those I would know

were laser cut.

Q. And how would you know that the TVT Securs were laser cut?

A. Because all the TVT Securs are laser cut.

Q. And when you are excising or removing or releasing one of the Ethicon TVT meshes, how are you able to determine whether it is a TVT Secur, a TVT retropubic or a TVT obturator sling?

A. From the operative report.

Q. So, as I understand it, if you have the operative report you are able to determine whether it's retropubic, obturator or a mini-sling?

A. Correct.

Q. Sometimes you have the product code?

A. Correct. And sometimes, as I have had a few are Exact, and then I would know that it is a laser-cut mesh because all Exacts are laser cut.

Q. And without having the benefit of the operative report or the product code, how are you able to determine whether a TVT mesh is TVT retropubic, TVT obturator or TVT Secur?

A. Well, it's very -- it's relatively easy to tell a retropubic from a obturator, because the

retropubic quickly goes up, you know, towards the urogenital diaphragm underneath the urethra. The obturators go lateral out to the obturator foramen, so it's easy to tell a retropubic from a obturator foramen.

Whether or not it is a mini-sling, you can feel that, particularly with the Secur, because there is no anchor into the obturator muscle or the obturator foramen. The sling ends at the obturator foramen or, excuse me, the obturator internus muscle.

MR. ROSENBLATT: I want to go ahead and mark as Exhibit 3 what's been marked as the notice of deposition.

(Rosenzweig Exhibit 3 was marked for identification as of 2/4/16.)

BY MR. ROSENBLATT:

Q. Am I correct that you brought a copy of this notice with you?

A. Yes, I did.

Q. And it says -- strike that.

If you could turn with me to Page 3 under document request.

A. Yes.

Q. I'm looking at number 4. It says a copy of your complete file in this case. Did you bring a copy of your complete file in this case?

A. No. From my understanding, that's going to be made available to you electronically.

MR. ROSENBLATT: Counsel, you can verify that.

MR. WALDENBERGER: Are you defining case as the McGee case or are you defining case as -- how are you defining case? I guess that's the interesting way of answering your question, because if it is the McGee case, he doesn't have any McGee documents.

MR. ROSENBLATT: The complete case file for TVT Secur.

MR. WALDENBERGER: Yeah, sure.

MR. ROSENBLATT: Okay. Counsel, you will make that available electronically?

MR. WALDENBERGER: Yes.

MR. ROSENBLATT: I would ask if there are any highlighted documents that we have the benefit of the highlighted documents whether you want to scan those in or however you want to do that.

MR. WALDENBERGER: To the extent any exist, sure. I don't know whether any do or not.

BY MR. ROSENBLATT:

Q. Doctor, when you review the literature do you manually highlight your literature?

A. There are times that I do, there are times that I don't.

Q. Do you recall whether or not you highlighted any TVT Secur literature?

A. In this case?

Q. We are here talking about TVT Secur. I'm wondering if you have highlighted any TVT Secur medical literature that would assist you in supporting your opinions?

A. In this case?

MR. WALDENBERGER: Are you talking ever, has he ever done it?

MR. ROSENBLATT: In any TVT Secur case.

A. Yes, I might have.

Q. And would you be able to make those highlighted articles available to your counsel to provide to us?

A. I can try to do that.

Q. And would you have highlighted any TVT Secur company documents to support your opinions in any TVT Secur case?

A. I might have done that.

Q. Again, the same request, if you could provide those to your counsel and if we could get copies of those.

A. I can try to do that.

Q. Doctor, number 5, it says, "All documents, including but not limited to calculations, correspondence, data, calendar entries, notes and other materials reflecting the compensation paid to you for study and testimony in this case."

Do you see that?

A. Yes.

Q. And have you brought any documents to that effect with you today?

A. I have not submitted any bills for this case.

Q. Did you bring any bills or invoices with you at all?

MR. WALDENBERGER: You can answer that

question, and then I'm just going to put an objection on the record, but you can answer that.

A. No.

MR. WALDENBERGER: And Paul, as you know, when you e-mailed me, I objected to this particular request because it was outside the scope of this particular deposition, which is why he doesn't have any of those materials here.

MR. ROSENBLATT: And I will just put on the record as well that my understanding is in the Carlino case Judge Powell said we could cite to him as precedent that he is requiring experts to produce all of their invoices.

So, I'm just renewing my request for those documents, and we can revisit that issue, but your objection is noted, and we would like to continue pursuing those documents.

MR. WALDENBERGER: Sure.

BY MR. ROSENBLATT:

Q. But Doctor, you do have a copy of all of your invoices that you could provide to your

counsel?

A. For this case?

Q. For your work in all the pelvic mesh litigation.

A. No, I don't.

Q. I believe counsel could gather that together, though, if need be.

A. That would be quite difficult for all of the pelvic litigation.

Q. How many invoices --

MR. WALDENBERGER: He hasn't asked you a question, so we will stop there.

BY MR. ROSENBLATT:

Q. How many invoices would you say you have submitted in the pelvic mesh litigation?

A. Over the last five years?

Q. Yes.

MR. WALDENBERGER: I'm going to object to the extent that it is outside the scope of this particular deposition, but I'm going to let him answer that.

A. I don't know.

Q. Including the -- strike that.

How many hours have you spent preparing

for your opinions in any TVT Secur case?

A. In any TVT Secur case? I don't -- I don't even have an estimate.

Q. How many hours did you spend preparing for this deposition?

A. Approximately 22 hours.

Q. And you said you have not submitted a bill for that?

A. Correct.

Q. And for those 22 hours, how much of that would be meeting with your attorney?

A. Approximately seven hours.

Q. And of those seven hours, was that all in one day?

A. Correct.

Q. And when was that?

A. Yesterday.

Q. And who did you meet with?

A. The two gentlemen sitting here.

Q. And so the other 15 hours, was that spent working on your expert report?

A. Correct.

Q. Doctor, let me go ahead and mark this while it is in front of me. I'm marking as Exhibit

4, this is the supplemental expert report that you submitted in this case?

A. Correct.

(Rosenzweig Exhibit 4 was marked for identification as of 2/4/16.)

BY MR. ROSENBLATT:

Q. And you brought a copy of this expert report with you as well?

A. Correct.

Q. And if we turn to Page 26, that's your signature there?

A. Correct.

Q. And this was served January 15th or strike that.

This is dated January 15th, 2016?

A. Correct.

MR. ROSENBLATT: I may go back to that in just a minute.

Go ahead and mark as Exhibit 5, a supplemental reliance list in the McGee case.

(Rosenzweig Exhibit 5 was marked for identification as of 2/4/16.)

BY MR. ROSENBLATT:

Q. This is the supplemental reliance list

that we received a few days ago. Did you ask your attorney to include any additional studies or documents that are now included in this list?

A. I did not.

MR. WALDENBERGER: Just so you know, Paul, we prepared this list.

MR. ROSENBLATT: Okay.

MR. WALDENBERGER: And the stuff on the end, there is a KM Bates stamp. That's because when we looked at the list we maybe saw that those weren't included before. That may be duplicative, but we re-Bates-stamped with a "KM" in an abundance of caution. There may be things that were on the other list, but it is so big that we would just like to err on the side of caution.

MR. ROSENBLATT: I appreciate that.

BY MR. ROSENBLATT:

Q. Doctor, just speaking in general terms, if there was a device that could positively affect incontinence issues for women, would that be a good thing?

A. Hypothetically?

Q. Yes.

A. Hypothetically, yes.

Q. And would you say ideally or hypothetically you would agree that less invasive is better than more invasive?

A. That statement I can't answer because there are many different things that go into a distinction between less invasive and more invasive.

Q. So, you can't answer whether or not it would be ideal to have a less invasive procedure over a more invasive procedure?

MR. WALDENBERGER: Objection, asked and answered. I think he just explained to you. If you want to qualify your question or add some components to it, but I'm not instructing him not to answer, so you can answer.

A. Again, without more information, I can give you an example of something that's less invasive, such as putting an IV in and then injecting chemotherapy, that has --

Q. And --

MR. WALDENBERGER: Let him finish.

A. That can be quite risky versus a

surgical, an invasive surgical procedure.

Q. And Doctor, I think I said I was speaking in general terms, but speaking in general terms related to treatment for stress urinary incontinence.

A. And again, with the same qualifiers, without more information it would be very difficult to answer that question.

Q. And you would agree that in general no exit wounds is better than exit wounds?

A. Again, in that are we talking about gunshots or --

MR. WALDENBERGER: Or are we talking about stress urinary incontinence treatment?

A. Because if you have a through-and-through gunshot wound, that's probably more preferable than no exit wound because then the bullet is bouncing around in someone's body.

MR. WALDENBERGER: I think he is going to rephrase his question.

Q. Doctor, I have got a list of questions here, and they are all related to incontinence surgery in general.

A. Okay.

Q. Is that enough of a qualifier there?
A. Excellent.
Q. So, with that understanding, would you agree that no exit wounds is potentially better than exit wounds?
A. Not necessarily.
Q. And why is that?
A. Again, without more information about what is taking place with the exit wounds, it would be very difficult to answer that even in a general hypothetical sense.
Q. And again, generally speaking about SUI surgeries, you would agree that it's a benefit to be able to accommodate patients who are concerned with any type of cosmetic scarring?
MR. WALDENBERGER: Objection to the form, vague. You can answer if you understand it.
A. Again, without anything more than just cosmetic scarring, I can't answer that question.
Q. Have you ever had any patients come to you who were concerned about scars that they may have on their abdomen or pubic area from an incontinence surgery?

A. If they are a keloid former, which means that they have an exaggerated scar, they would be concerned about that, yes.

Q. And there may be some women who may be a model or they are just overly concerned about their appearance and wouldn't want any type of scar, correct?

A. That is a possibility, yes.

Q. And so you agree it is potentially a benefit to have a procedure that could treat incontinence that would not leave a cosmetic scar?

MR. WALDENBERGER: Objection to form.

You can answer.

A. Again, without knowing anything more than just that hypothetical, I can't answer that question.

Q. And generally speaking, would you agree that less anesthesia is better than more anesthesia?

A. And we are talking about general anesthesia or we are talking about regional anesthesia or we are talking about local anesthesia?

Q. Let's talk about local versus general

for a stress urinary incontinence procedure.

A. Local anesthesia would be beneficial compared to general anesthesia.

Q. And you would agree that a quicker operation would be better than a longer operation?

A. And we are talking about what length of operation. Whether it's the difference between 15 minutes and 20 minutes wouldn't make a significant difference. The difference between 20 minutes and four hours would make a significant difference.

Q. And when you say it could make a difference, what is the reason behind that statement that there could be a big difference between the operative times?

A. Between 20 minutes and four hours?

Q. Yes.

A. The operation that's longer than two hours would increase the risk of deep venous thrombosis, postoperative pneumonia and postoperative infection.

Q. In your opinion, is there a significant difference between a 10-minute procedure and a one-hour procedure?

A. Potentially.

Q. And what would that difference be?

A. Well, usually within an hour you are going to have only a minimal risk of increasing the intraoperative morbidity from a procedure, so there probably is not a significant difference in the timeframe that you gave me.

Q. And that brings up another point. It would be beneficial to reduce intraoperative complications, if possible?

A. Yes.

Q. And if it was possible to make an operation quicker without introducing new risks, that would be beneficial?

A. Again, not necessarily.

Q. You would agree that it would be beneficial to be able to treat a patient with general stress urinary incontinence as well as ISD or intrinsic sphincter deficiency, correct?

MR. WALDENBERGER: Could you read that question back.

THE REPORTER: "You would agree that it would be beneficial to be able to treat a patient with general stress urinary incontinence as well as ISD or intrinsic

sphincter deficiency, correct?"

MR. WALDENBERGER: I object to the form of the question.

A. Well, intrinsic sphincter deficiency is a form of stress urinary incontinence.

Q. Have you seen studies that would indicate that a retropubic approach is better at resolving ISD than other approaches?

A. That has been suggested in the literature.

Q. And so you would agree that there would be some benefit to be able to perform either a retropubic procedure or an obturator procedure, depending on the type of incontinence a patient had?

A. I don't understand your question.

Q. You would agree that -- I will re-ask it.

You would agree that it would be a benefit to have a versatile procedure that would allow you to either perform it through the obturator or retropubically, depending on the type of incontinence a patient had?

MR. WALDENBERGER: Objection to the

form, vague. You can answer it if you understand it.

A. Again, I don't understand your question. I --

MR. WALDENBERGER: That's fine. He doesn't understand your question.

Q. You agree it would be a benefit if a woman was able to drive herself to and from an operation the same day, correct?

A. After surgical procedures our recommendation is that the patient would not drive themself home from the operation even if it is done under local anesthesia.

Q. But you would agree that that would be a benefit, correct?

A. I would not recommend any patient drive themself home after a surgical procedure even if it is done under local anesthesia.

Q. Would you agree that it's a benefit to have a patient leave the procedure that same day and go home as opposed to staying overnight in a hospital?

A. There is an economic benefit of a same-day surgery versus an overnight stay.

However, if you admit the patient as a 24-hour observation, that economic benefit is minimized and there doesn't appear to be a significant difference between a observation versus a outpatient procedure.

Q. Would you agree that it would be a benefit for a patient to undergo a procedure where she did not have to go home with a catheter?

A. Yes.

Q. You agree that it would be beneficial for a woman to undergo a procedure that would allow her to return to her normal activities quicker?

A. What normal activities are you talking about?

Q. Just generally speaking, walking, running, lifting, going back to work.

A. Going back to work would be an economic benefit. I'm not sure that walking -- most patients after any surgical procedure are encouraged to get up and walk as quickly after the surgical procedure as possible.

Q. Doctor, how do you define normal activities?

MR. WALDENBERGER: For himself?

MR. ROSENBLATT: Yeah.

MR. WALDENBERGER: How do you define your own normal activities?

BY MR. ROSENBLATT:

Q. When you are talking about a patient, how do you define normal activities?

A. So how do I counsel my patients about what -- when they can go back to work, when they can have sexual intercourse, when they can exercise or when I expect them to get out of bed and walk around? Because I expect my patient to get out of bed and walk around as soon after the surgical procedure as possible.

Q. So, you would agree it would be a benefit for a patient to be able to have sex sooner after a procedure than later?

MR. WALDENBERGER: Objection to the form, vague. I think it is relative to time, but you can answer if you understand that.

THE WITNESS: It would be beneficial to have intercourse sooner?

MR. WALDENBERGER: Do you understand the question?

THE WITNESS: No.

BY MR. ROSENBLATT:

Q. Do you agree it would be beneficial for a patient to undergo a procedure that would allow her to return to work faster than another procedure?

A. Return to work?

Q. Yes.

A. As an economic benefit, yes.

Q. And you would certainly agree that if there was a single mother who was the breadwinner, that that could be an important factor for that patient in considering her surgical options, correct?

MR. WALDENBERGER: I don't even know what to say. Objection, you can answer.

A. Well, most of my patients would fall under the economic umbrella that their surgical procedure is covered by their short-term disability, and so I don't see that that would be that significant unless they did not have that ability to be covered under short-term disability.

Q. You agree that less postoperative pain is better than more postoperative pain?

A. Yes.

Q. And that would be true for both the short term and the long term?

A. Yes.

Q. You would agree that less mesh is better than more mesh?

A. Mesh cannot create the chronic foreign body reaction, chronic inflammatory response, the degradation and contraction if it is not in a location. Now, the exact tissue response is the same at the -- where the mesh is.

Q. I appreciate that, Doctor. I'm not clear on your answer, so I'm hoping I can ask it again and maybe better understand your answer.

Yes or no: Would you agree that in general less mesh is better than no -- than more mesh?

MR. WALDENBERGER: Objection, asked and answered, and you do not have to limit your answer to yes or no. Please answer the question as you see fit as long as it is responsive to his question.

A. Mesh cannot create the chronic inflammation, chronic foreign body reaction, contraction, degradation and the effect on the

tissue that it has if it is not in that location, but the effect on the tissue is the same where the mesh is.

Q. But you would agree it would be beneficial to have less mesh because that would then mean that there is less of a reaction?

A. There is not less of a reaction. There is less of an area where that reaction is taking place.

Q. So, in your opinion is there any benefit to 8 centimeters worth of mesh as opposed to 40 or 45 centimeters worth of mesh?

A. Well, we know that not all 45 centimeters of mesh is in the body at the end of the surgical procedure. So, where the mesh is not is not going to undergo a chronic foreign body reaction, chronic foreign body, mesh contraction, mesh degradation, mesh deformation and the consequences of that, which is erosion, pain, dyspareunia, chronic pain, the need for chronic revision procedures; all the things that are illustrated in my report.

Q. Would you say that less mesh leads to fewer complications as opposed to more mesh leading

to more complications?

A. The mesh cannot create a complication where it isn't.

Q. Doctor, what I'm trying to get from you is whether or not you as a surgeon would see any benefit to treating a patient's condition with less mesh, less surface area, than more mesh, whether it's 8 centimeters versus 15 centimeters?

MR. WALDENBERGER: Is that a question? That sounded like a statement rather than a question.

MR. ROSENBLATT: I added a statement at the end.

MR. WALDENBERGER: So I don't know what the question, so let's start there.

MR. ROSENBLATT: I will strike that.

BY MR. ROSENBLATT:

Q. My question is, Doctor, do you see a benefit as a surgeon to implanting less mesh in a patient to treat stress urinary incontinence than implanting more mesh, or do you see no benefit?

MR. WALDENBERGER: Objection to the form, asked and answered several times. You can answer again.

A. I don't see any benefit to implanting mesh.

Q. And I understand that's your opinion. What I'm trying to pin down, Doctor, is whether or not there is a benefit to using less mesh or whether it doesn't matter if you use more mesh because you are going to have the same reaction?

MR. WALDENBERGER: Objection, asked and answered. You can answer again.

A. The mesh creates the same tissue response where the mesh is. It cannot create the same tissue response where it is not.

Q. Did you want to elaborate any more than that, or are you sticking to that answer?

MR. WALDENBERGER: Objection to the form. It's a perfectly appropriate answer to stick with, unless you have something to add. Anything to add? Are you good?

THE WITNESS: I'm good.

MR. WALDENBERGER: All right.

BY MR. ROSENBLATT:

Q. Doctor, would you agree that less mesh means less foreign body response?

A. In the places where there is no mesh,

there will not be a foreign body response.

Q. So is that a yes or a no?

A. In the area where there is no mesh, there will be no foreign body response.

Q. Doctor, are you unable to answer the question with a "yes" or a "no"?

MR. WALDENBERGER: He has answered the question, Paul, but you can ask it again.

Q. I said, are you unable to answer the question with a "yes" or a "no"?

A. The answer is that if there -- where there is no mesh, there will be no foreign body response.

Q. And my followup to that is, wouldn't you agree that that is a benefit to have less area where you would have a foreign body reaction?

MR. WALDENBERGER: Objection, asked and answered. You can answer it again.

A. You will not have the consequence of the foreign body reaction where the mesh is not.

Q. Doctor, would you agree that less mesh means less inflammation and less mesh left behind?

MR. WALDENBERGER: Objection, compound. You are asking about inflammation.

MR. ROSENBLATT: I will break it down for your counsel.

MR. WALDENBERGER: And for him, but thank you.

BY MR. ROSENBLATT:

Q. Do you need me to separate those two?

A. Yes, please.

Q. I will. Doctor, would you agree that less mesh means more -- strike that.

Doctor, would you agree that less mesh means less inflammation?

A. There will not be inflammation where the mesh is not.

Q. So you can't answer that with a "yes" or a "no"?

MR. WALDENBERGER: Objection to the form. You can answer.

A. There will not be inflammation where the mesh isn't.

Q. And you would agree that that's a benefit if you don't have inflammation in certain areas where you might if you had more mesh?

MR. WALDENBERGER: Objection to the form.

A. If the mesh cannot create the chronic inflammation, the chronic foreign body reaction, scar plate formation where the mesh is not.

Q. Doctor, would you agree that less mesh left behind is a benefit compared to more mesh left behind?

A. More mesh left behind will be more areas where the mesh is creating chronic foreign body reaction, chronic inflammation, chronic scar-plating and irritating more nerves than an area where there is less mesh.

Q. And now that we have established that, would you agree that that would be a benefit to have less of a foreign body reaction?

A. The foreign body reaction where the mesh is is going to be the same. If there is no mesh in another location, there will not be a foreign body reaction where the mesh is not.

Q. And you would agree that that would be a benefit?

A. No, because of the area where the mesh is you are getting chronic foreign body reaction, chronic inflammation, scar plating, nerves being injured and all of the responses or all of the

complications that I highlight in my report.

Q. Doctor, have you ever issued the opinion that the TVT Abbrevo is safer than the TVT-O?

MR. WALDENBERGER: Objection. How is that within the scope of this deposition?

MR. ROSENBLATT: It is within the scope of the deposition because I'm talking about sling length here and he has not answered my question, so...

MR. WALDENBERGER: He has answered the question just fine.

MR. ROSENBLATT: I'm making a comparison here.

MR. WALDENBERGER: I will let him answer the question.

A. The Abbrevo is 12 centimeters. It goes through the obturator internus, the obturator foramen, the obturator externus muscle.

There is no mesh that is in the obturator -- or excuse me -- the adductor longus, the adductor brevis; and therefore, there would not be that irritation of those muscles, there would not be the irritation of the obturator nerve from the Abbrevo.

MR. WALDENBERGER: What number is this? Five, six.

MR. ROSENBLATT: I have just handed you what we have marked as Exhibit 6.

(Rosenzweig Exhibit 6 was marked for identification as of 2/4/16.)

BY MR. ROSENBLATT:

Q. And just hang on to that for a second, Doctor, but first I have a question.

Is a smaller area of chronic foreign body reaction a better result than a larger area?

A. The foreign body response will be the same in the smaller area. It's just that it is where the mesh is not you would have -- you would not have a chronic foreign body reaction.

Q. And you agree that that would be a benefit?

A. For the area where there is no chronic foreign body reaction, yes.

Q. So are you saying that there is no difference if the mesh is present?

A. You cannot have a chronic foreign body reaction, degradation, contraction where the mesh is not.

Q. Doctor, if you have pain in your big toe and you have a headache -- strike that.

I have handed you what's been marked as Exhibit 6. Do you recognize this document?

A. Yes.

Q. And please tell us what this document is.

A. This is a fourth supplemental report in the Huskey, et al., case in the West Virginia MDL.

Q. And you recall that the Huskey case was a TVT-O laser-cut case?

A. Correct.

Q. And in this supplemental report I believe you stated that Ethicon had a safer option for patients other than the TVT-O in the Abbrevo sling, is that correct?

A. Correct.

Q. And I understand it's your opinion that no mesh should be used in the pelvic floor, correct?

A. Correct.

Q. And you stand by that statement today?

A. Correct.

Q. And you also said in your report that

the Abbrevo sling has less mesh than the TVT-O, which means less foreign body response, less inflammation and less mesh left in the adductor muscle, resulting in less chronic pain, chronic groin pain and chronic pelvic pain for the patient, correct?

A. Correct.

Q. And you still stand by that today?

A. As I was saying, you cannot get a chronic foreign body response, chronic inflammation in the adductor muscles because there would be no mesh in the adductor muscles.

Q. And part of your opinion that support -- or strike that.

So, your opinion in the Huskey case was that the TVT Abbrevo laser-cut, 12-centimeter mesh was a safer option than the longer TVT-O laser-cut mesh?

A. For Ms. Huskey, yes.

Q. And what specific to Ms. Huskey would differentiate your opinion from, say, another patient?

A. Well, she was having pain from irritation of her obturator nerve and the chronic

foreign body reaction and chronic inflammation of the tape left in the adductor muscles lying next to the obturator nerve was leading to her chronic obturator nerve pain and her chronic leg pain.

Q. So you can't make a general statement that TVT Abbrevo is safer than TVT-O laser cut?

A. The effect of the Abbrevo with the chronic foreign body reaction, chronic inflammation, degradation, contraction in the vagina is going to be the same.

Q. I don't think you are answering my question here, so I'm going to keep trying until you do. Is it true that you cannot make a general statement that the TVT Abbrevo is a safer option than the TVT-O laser-cut mesh?

MR. WALDENBERGER: Paul, why is this inside the scope of a TVT-S deposition?

MR. ROSENBLATT: I'm making a comparison to his previous opinion about how a shorter mesh is safer than a longer mesh when they are both laser cut, and here we are talking about a even shorter mesh and all he is saying is, well, you are going to have a reaction if there is mesh there and won't

answer the question wouldn't that be a benefit if there is less mesh even though you have the same reaction in that area.

MR. WALDENBERGER: He has answered all of those questions inside and outside the context of both the TVT-S and his fourth supplemental report.

So, I'm really not clear where you are going with this, but I will let it go on for a few more questions, but I really do think it is outside the scope of the TVT-S. So, if you could ask a question, take it from there.

BY MR. ROSENBLATT:

Q. Doctor, which product would you say is safer: The TVT Abbrevo or the TVT-O laser cut?

MR. WALDENBERGER: Objection. Don't answer. Outside the scope of this deposition.

Q. Are you going to answer?

MR. WALDENBERGER: I'm instructing him not to.

Q. Doctor, which product is safer: The TVT Abbrevo or the TVT Secur?

MR. WALDENBERGER: Objection to the form. You can answer.

A. Between the two, I don't think that one is safer.

Q. Doctor, between TVT Secur and TVT-O laser cut, which product is safer?

MR. WALDENBERGER: Objection to the form. You can answer.

A. The TVT Secur, there would be no mesh left in the adductor muscles, resulting in less chronic leg pain, chronic groin pain, chronic pelvic pain.

Q. And I take it you would see that as a benefit over the TVT-O?

A. There would be less mesh left in the adductor muscles, so there would be no chronic foreign body response, no inflammatory response in the adductor muscles. There would be minimal chance of irritating the obturator nerve.

Q. And you would agree that that would be a benefit?

MR. WALDENBERGER: Objection to the form. Paul, your use of the terms like "safe" and "benefit" over and over and over again, implying that he has an opinion that these things are safe or have some type of benefit.

And I know that he has given it in terms of a comparison, but you keep asking him that way and --

BY MR. ROSENBLATT:

Q. Well, let me put a little caveat in here. With the understanding that you think no mesh should be used for stress urinary incontinence repair, with that understanding, can we work with that?

A. Yes.

Q. With that understanding, would you agree that less mesh is better than more mesh if you had to use mesh?

MR. WALDENBERGER: Paul, we have gone over the less mesh and more mesh thing.

MR. ROSENBLATT: If he answers my question, I could move on.

MR. WALDENBERGER: He has told you time and time again when you have more mesh, you have more foreign body reaction. You have less mesh, you don't have the reaction with the --

MR. ROSENBLATT: He hasn't said that, he hasn't said that.

BY THE WITNESS:

A. Where the mesh is not, there is no foreign body reaction, there is no inflammation, there is no scar plating, there is no degradation there is no contraction.

BY MR. ROSENBLATT:

Q. Right. And a smaller area where you are having that same reaction would be better than a larger area where you are having that same reaction?

MR. WALDENBERGER: Objection, asked and answered.

A. As I state in my report, there would be no inflammation, no mesh left behind in the adductor muscles with a shorter mesh.

Q. So, I'm going to try to make this very simple. Do you or do you not see any benefit to having a shorter mesh?

A. A shorter mesh means that there is no mesh left behind in the adductor muscles outside the obturator externus muscle; therefore, there would be less leg pain, groin pain for the patient.

Q. So you can't answer that question?

MR. WALDENBERGER: He just answered

the question. Move on, Paul.

BY MR. ROSENBLATT:

Q. But you can't answer it -- and I'm fine with moving on, but you can't answer that with a yes or no, can you?

MR. WALDENBERGER: He answered the question. He actually described what he was talking about, so he answered the question.

MR. ROSENBLATT: Without answering the question.

MR. WALDENBERGER: He answered the question just fine. He has answered the question. Move on to the next one.

BY MR. ROSENBLATT:

Q. Doctor, between -- strike that.

We are still talking about the same caveat here, that you do not think any mesh used for stress urinary incontinence is a safe option, correct?

A. Correct.

Q. With that understanding, between TVT Secur and TVT retropubic mechanically cut, in your expert opinion is one safer than the other?

MR. WALDENBERGER: Objection to form,

asked and answered. You can answer.

A. Mechanical cut mesh leads to roping, fraying, curling, which leads to a certain set of complications. TVT Secur is a heavyweight, small pore, laser-cut, short mesh, which is stiffer, which leads to a certain set of complications.

Q. And what are you relying on for that statement that a stiffer mesh leads to more complications?

A. The Liang paper, the Moalli papers, the Bosse papers showing that stiffer mesh increases cell death, which will increase erosions; leads to vaginal thinning; leads to smooth muscle damage, which will lead to stress urinary incontinence; leads to poor collagen functioning, which will lead to -- also, their latest study shows that you have an induction of bad macrophages, which will lead to more of a chronic inflammatory response, more scar plating -- I will slow down a little bit -- more muscles being -- excuse me -- more nerves being irritated; therefore, more erosions, more pain, more dyspareunia and all of the other risks that I've cited in my report.

Q. Would the TVT -- strike that.

In your opinion, would the TVT Secur be a safer mesh if it was mechanically cut instead of laser cut?

MR. WALDENBERGER: Objection to the form. You can answer.

A. No. A safer, a safer --

MR. ROSENBLATT: You see how he answered that with a "yes" or a "no"? That was incredible.

A. A safer mesh would be a larger pore, lighter weight mesh that was laser cut.

MR. ROSENBLATT: Can you read that answer back for me.

THE REPORTER: "No. A safer, a safer --

"Mr. Rosenblatt: You see how he answered that with a 'yes' or a 'no'? That was incredible.

"Answer: A safer mesh would be a larger pore, lighter weight mesh that was laser cut."

BY MR. WALDENBERGER:

Q. Doctor, would you agree that there is a benefit to mesh being cut with a laser?

A. A larger pore, lighter weight mesh or for less mesh left behind on the cutting room floor?

Q. Can you not answer the question the way I phrased it?

A. I'm wondering what benefit you mean.

Q. Okay. I want to play a little game. We are going to change one component, and I want to see how that affects your answer, and the three components we are dealing with are the pore size, the weight, how the mesh is cut.

A. Okay.

Q. And we are still operating under the assumption that no mesh in your opinion is the best mesh.

A. Yes.

Q. If you only increase the pore size of TVT Secur and left everything else the same, would that make it safer?

A. A larger pore, lighter weight mesh would be the safer mesh.

Q. But you didn't understand my question. We are keeping the weight the same. We are only making the pore size bigger.

A. A lighter weight, larger pore mesh would be the safer mesh.

Q. So you can't answer the question if we only increase the pore size but the weight stays the same?

A. A larger pore, lighter weight mesh would be safe.

Q. Doctor, you cannot answer the question only focusing on the pore size, correct?

A. A lighter weight, larger pore mesh would be safe.

Q. So is the answer you can't answer that question?

MR. WALDENBERGER: The answer is that's what his answer is. Again, your use of the term "safe," even if you put this caveat on it, which is fine, but your use of the term "safe" has certain implications. And I understand why you are doing it. It's because you can have a transcript, you can cut that particular part out, you can cross-examine that he used the word "safe" when he answers with the word "safe." But he is giving this answer to this question.

MR. ROSENBLATT: He is giving opinions about whether something is safer or not, and he is saying that Ultrapro is safer than TVT Secur, so I'm --

MR. WALDENBERGER: And that's consistent with what he just testified right now.

MR. ROSENBLATT: Right.

MR. WALDENBERGER: Correct. So we are in agreement.

MR. ROSENBLATT: Please limit your objection to form and let me handle this here.

MR. WALDENBERGER: I will object and interject as I see fit, so let's continue.

MR. CAMPBELL: We have been at it for more than an hour since the last break, so I'm happy to have just a 10-minute break.

MR. WALDENBERGER: Sure.

(Recess taken, 11:26 - 11:45 a.m.)

(Rosenzweig Exhibits 7 through 13 were marked for identification as of 2/4/16.)

BY MR. ROSENBLATT:

Q. All right, Doctor. We are back from a

quick break here. If you could pull out in front of you Exhibit 4, which is your expert report.

A. Yes.

Q. At the top it says that all of your opinions are held to a reasonable degree of medical certainty. What does that mean?

A. Reasonable degree of medical certainty?

Q. Yes.

A. That the probability is greater than 51 percent.

Q. And you see here the summary of opinions, it lists "A" through letter "N"?

A. Yes.

Q. Is that a fair representation of your opinions regarding the TVT Secur in this case?

A. Correct.

Q. And this would be in addition to your opinions listed in your general report?

A. Yes.

Q. But my understanding is these opinions are specific to the TVT Secur?

A. Yes.

Q. If you could, just tell me what your expert opinions are in this case.

MR. WALDENBERGER: Relating to the Secur, you mean?

MR. ROSENBLATT: Yes.

A. As I stated in my report, I go over what are the defects in not only the design but the warnings of the TVT Secur and the harms that are associated with those defects.

Q. And what are your opinions about the design defects?

A. That the laser cutting of a small mesh, which is heavyweight, small pore, of a 6-mil fiber size leads to rigidity and stiffness. I think we have also discussed degradation, contraction, chronic foreign body reaction.

That the introducer is of a design that increases the risk of injury, the introducer being the arrow shape of the introducer, and that the introducer has a difficulty of getting into the right position and into the right location and removal; that upon dislodging the introducer you can or removing the introducer you can dislodge the sling, which will decrease its ability to lead to stress urinary incontinence.

The Ethisorb fleece end, Ethisorb,

E-t-h-i-s-o-r-b, fleece end does not allow for fixation to adequately allow, quote-unquote, tissue integration, therefore increasing the chances of recurrence of stress urinary incontinence.

The size of the introducer is large for the description of the incision size, which therefore leads to a dragging of either periurethral or perivaginal tissue, which leads to tissue disruption and also tissue damage which will lead to pain and dyspareunia.

The depth of the incision needs to be deeper so that the mesh will lay flat and be able to be introduced in a way that decreases tissue disruption and tissue irritation and the mesh to lay flat to decrease complications.

The IFU does not adequately describe the way to -- the incision, the depth of the incision, and how to properly, quote-unquote, tension the mesh, which needs to be placed, quote-unquote, with more tension than the standard TVT or TVT-O.

There needs to be, quote-unquote, pillowing of periurethral tissue between the pores at the time of insertion in order to be able to get the mesh in the appropriate location to treat

stress urinary incontinence.

The TVT Secur is a more difficult sling to insert, therefore needs a increased level of skill than the average surgeon in order to get a adequate success rate and to minimize complications.

That is a brief summary of all the opinions that are further stated in more detail in my report.

Q. But it's fair to say that your opinions that you plan to offer are contained within this supplemental report?

A. Correct.

Q. What are all of the complications that you believe come about due to the design of TVT Secur?

A. As I've described in my report, the list of complications include erosion, pain, urinary problems, erosion that can decrease the quality of life, dyspareunia, need for additional surgery, need for removal surgery, urinary tract infections, dysuria, de novo urgency, mesh exposure, fistula formation, hematomas, abscess formation, narrowing of the vaginal walls, erosion that can occur at any

time during the patient's life, mesh contracture causing pain, complications that make it impossible to have sexual intercourse beside the others that I've described that are associated with the polypropylene mesh in general.

Q. Are there any unique complications related to the TVT Secur that would not occur with any of the other Ethicon TVT products?

A. Are you talking about the performance of the Secur, the surgical procedure versus the surgical procedure or complications in general?

Q. Right now I'm focused on complications.

MR. WALDENBERGER: Meaning the injury to the person?

MR. ROSENBLATT: Yes.

MR. WALDENBERGER: Do you understand it that way?

THE WITNESS: No.

BY MR. ROSENBLATT:

Q. Okay. So, when we say complications, what are you referring to?

A. Well, I mean, there can be complications meaning adverse events to the patient and there can be complications meaning difficulty with the

surgical procedure.

Q. Okay. I'm focused just on the patient. So, in terms of complications that can occur to the patient, what are the unique complications that can occur with TVT Secur that are not associated with any of the other TVT products?

A. As I described in my report, all the complications that are associated with TVT Secur were known prior to the time that the Secur was placed in the market.

Q. And I think you answered a different question. You said that those complications were known. I'm asking what, if any, are the unique complications that a patient might experience with a TVT Secur that she would not experience with any other Ethicon TVT product, or your answer could be all the complications are the same.

A. I would say all the complications are the same.

Q. Okay. Are there any complications that could occur to the patient that you believe happen at a greater frequency or severity than any of the other TVT products?

A. Yes.

Q. And what are those?
A. Erosion, bleeding and dyspareunia.
Q. Any others?
A. Failure and the need to reoperate for recurrent stress urinary incontinence or treatment for recurrent stress urinary incontinence.
Q. Are you aware of any studies showing no statistical significance between the rate of erosions when comparing TVT Secur to any of the other TVT products?
A. Am I aware that there are studies that show there are no differences?
Q. Yes.
A. Yes.
Q. How many studies are you aware of that show no difference?
A. The exact number I do not recall off the -- sitting here today.
Q. Can you recall any?
MR. WALDENBERGER: Meaning the title?
MR. ROSENBLATT: Yes, author, year.
A. The Anders Hamer study did not show a difference between vaginal erosions, if I recall, but did show a much higher rate of urethral

erosions.

Q. Any others?

A. The Tommaselli study, I mean, there are studies that have shown that there was a similar erosion rate.

Q. I will ask the same question about bleeding. Are you aware of any studies comparing TVT Secur to any of the other TVT products that showed no statistical significance with respect to bleeding?

A. Many studies did not talk about bleeding specifically.

Q. But are you aware of any that did talk about it that determined that there was no statistical significance?

A. Yes.

Q. Are you able to name any of those studies right now?

A. It's not described in the Hota study, the Masta -- the Masata study and several other studies.

Q. Same question for dyspareunia: Are you aware of any studies comparing TVT Secur to any of the other TVT products that found no statistical

significance with respect to dyspareunia?

A. Yes.

Q. And can you list those studies for me?

A. There are a number of studies, the exact names. There is the Tommaselli studies that didn't show any difference between dyspareunia; Barber study that didn't show any difference in dyspareunia, just to name a couple.

Q. And how do those studies affect your opinion as far as TVT Secur causing more erosions, bleeding and dyspareunia?

A. Than the other slings that we are talking about, right?

Q. No. I'm asking -- let me back up here. You previously told me that TVT Secur experiences more erosions, bleeding and dyspareunia. Is it your opinion that there is a statistically significant increased risk of erosion, bleeding and dyspareunia with TVT Secur as opposed to the other TVT products?

A. The Cochrane analysis that was done in 2014 showed that there was a adverse event profile noted significantly worse and higher rate of operative blood loss, mesh erosion and bladder and

urethral erosion.

Q. Other than the Cochrane review, what else are you relying on?

A. The Cochrane review, which is a systematic review.

Q. Anything else?

A. My review of the literature.

Q. How much more likely is a patient to experience a mesh erosion with a TVT Secur as opposed to any of the other TVT products?

MR. WALDENBERGER: Objection to the form. You can answer.

A. As I've stated, that there is a probably 10 to 15 percent risk. According to Tommaselli's systematic review, there was a 15 percent risk of erosion from TVT Secur, which would be approximately three times higher than the risk for the other TVT products.

Q. So doing basic math, it's my understanding that you would consider the other TVT products to have about a 5 percent mesh exposure rate?

A. 4 to 5 percent, yes.

Q. Are you aware of studies that have shown

no difference in failure rate between TVT Secur and any other TVT mesh?

A. We have already discussed that. That would be the opposite of the success rate. We have talked about the efficacy.

MR. WALDENBERGER: You can answer his question more specifically.

A. Yes, there are studies that look at failure rate, and have shown similar failure rates.

Q. And would the same be true for reoperation rates?

A. If it doesn't fail, you wouldn't need to do a reoperation.

Q. Have you seen any studies that showed no statistical difference in reoperation rates between TVT Secur and any other TVT mesh?

A. Specifically looking at reoperation rates, I don't specifically recall those studies, but if you look at failure rates and then failure necessitating a reoperation, then there are studies that show a similar failure rate.

Q. And if you turn to Page 5 of your report, looking at the big paragraph there --

MR. WALDENBERGER: Let me catch up

with you, hold on.

MR. ROSENBLATT: Sure. Starting with "It was unreasonable on Ethicon's part to expect surgeons..."

MR. WALDENBERGER: Yes.

BY MR. ROSENBLATT:

Q. All of the complications that you list there, is it correct that you believe all of those complications should have been in the TVT Secur IFU?

A. Contraction, degradation, chronic pain, dyspareunia, unable to treat pain, injury to the partner in sexual intercourse, vaginal narrowing, vaginal scarring, fibrosis, scar plate formation deformation, yes.

Q. Hypothetically, if all of those were listed in the IFU, would you then think that the IFU was adequate and sufficient?

A. In respect to warnings?

Q. Yes.

A. If all the warnings that I described in my report that were not in the IFU, then I would find -- and if it talked about frequency, severity, treatability, permanency and described how to treat

the complications, then yes.

Q. So if I were to copy and paste this paragraph that you have here and put it in the IFU, that would still be inadequate in your opinion?

A. It would need to describe frequency, severity, treatability, permanency and a description of treatment, all of the things that I've described in my report that the warnings are inadequate.

Q. And are you able to provide me with the frequency percentage for each of these complications listed here that are specifically related to TVT Secur?

A. There are some that I can recall from the literature. I would say that the manufacturer is the one that would know about the complications of their product and, therefore, should be able to supply doctors with the frequency, with the severity, with the treatability and the permanency of the device.

Q. Let's walk through each one of these briefly, and you just let me know if you can tell me what the frequency is that you believe should be in the IFU, and then we will move on to the next

one. So, we will start with mesh shrinkage and contraction. Do you have a specific frequency for mesh shrinkage and contraction that occurs with TVT Secur?

A. Yes, all mesh slings and contracts.

Q. I'm asking about specifically about TVT Secur.

A. All mesh including the TVT Secur shrinks and contracts.

Q. What percentage?

A. All mesh shrinks and contracts.

Q. By how much is what I'm asking for, the frequency.

A. Well, I will use Dr. Arnaud's rule of thumb. That has been described as a 30 percent contraction rate. It has been described as even higher than that, up to a 50 percent contraction rate.

Q. And you as a pelvic floor surgeon would want to rely on Dr. Arnaud's statement?

A. Dr. Arnaud is one of the medical directors of Ethicon, has significant information about the performance of the product; and if he feels that a 30 percent contraction rate is a -- is

a rule of thumb for contraction, I would agree with that. It has been described as being higher, up to 50 percent, but Dr. Arnaud says the rule of thumb is 30 percent contraction.

Q. What level of evidence would you consider Dr. Arnaud's rule of thumb?

A. What level of evidence? He is a medical director at Ethicon, and he has information about the literature, about the performance of his products, so I would say that someone who is a medical director should have a very high level of evidence.

Q. And what is your understanding of the literature of the frequent receive mesh shrinkage and contraction with TVT Secur?

A. From the literature?

Q. Yes.

A. I have not seen a description of mesh, that a randomized control trial has looked at, TVT Secur at the time of placement and then following it up with ultrasound over time to show the level of contraction.

Q. What is the frequency based on the medical literature of degradation with TVT Secur?

A. All mesh degrades.

Q. To what extent does the TVT Secur degrade?

A. Well, it depends on the time of degradation. According to PA Consulting that issued a report after reviewing the literature to Ethicon, they state that all mesh degrades and degradation starts at implantation.

Q. And your opinion isn't limited to TVT Secur, but that would be all mesh?

A. Correct.

Q. What is the frequency based on the medical literature that you would attach to chronic pelvic pain for TVT Secur?

A. The Anders Hamer paper showed 13 percent chronic pelvic pain or pain associated with the TVT Secur.

Q. Is that the highest percent you have seen for chronic pelvic pain?

A. In the meta-analysis by -- and I'm blocking the name right now -- Muretti -- no. Masati -- we've discussed it at the other depositions -- shows that it is as high as 15 percent.

Q. In TVT Secur?
A. In midurethral slings.
Q. We are just talking about TVT Secur.
A. I would add TVT Secur in that, Masati.
Q. So when you are describing the frequency that should be in the IFU, you think the highest purported frequency in the medical literature should be the number that's attached to the complication?
A. I think that would be very important for doctors to be able to tell their patients what the worst-case scenario would be.
Q. And so these figures that you are providing for me, would it be fair to say that they are worst-case scenario?
A. There are some. There are some that would be averages.
Q. Okay. So we will move to dyspareunia. What is the frequency percentage that you would attach to dyspareunia for TVT Secur?
A. We have already discussed that.
Q. You said 8 to 10 percent?
A. Correct.
Q. What about for untreatable and permanent

pain?

A. If you look at the literature for patients that have been treated for pain, the untreatability for pain is anywhere from 20 to 40 percent, so patients --

Q. For the TVT Secur?

A. For midurethral slings.

Q. Okay. I'm just talking about TVT Secur.

A. And I would add TVT Secur into that.

Q. So 20 to 40 percent?

A. Of patients that have chronic pain, the inability and the permanency of the treatment.

Q. What is the frequency that you would attach to partner penile injury with intercourse related to the TVT Secur?

A. I don't know if there is a number that has been placed in the literature. That should be a number that the manufacturer should have from complaints that they have been given.

Q. Have you reviewed those documents?

A. No, I have not.

Q. And what is the percentage of vaginal scarring that you would attach to the TVT Secur?

A. Again, I have not seen that number

described in the literature, but that should be information that the manufacturer has.

Q. What about narrowing?

A. Same answer.

Q. Shortening?

A. Same answer.

Q. Fibrosis?

A. Same answer.

Q. Scar plate formation?

A. All mesh causes scar plate formation.

Q. Deformation?

A. Deformation, that is information that the manufacturer should have.

Q. The safety and effectiveness of the TVT Secur has not been evaluated in either long-term clinical studies or randomized controlled trials?

A. Long-term, yes.

Q. And you describe long-term as --

A. Five to ten years.

Q. Are you aware of any five-year studies evaluating the TVT Secur?

A. I think there was one Tommaselli study that was a five-year study.

Q. Are you aware of any others?

A. I think there was one or two others.
Q. So does that statement still stand?
A. Those were not randomized control trials, if I remember correctly.
Q. So, your testimony is that you are not aware of any randomized controlled trials that have followup that goes out to five years?
A. Not that I specifically recall.
Q. But if you were aware of such a study, that would be an important study to add to your reliance list, correct?
A. Yes.
Q. The necessity of multiple surgeries to remove mesh; what is the frequency of mesh removal for TVT Secur?
A. That would be based on the complications of pain, erosion, dyspareunia. So, if you look at the treatment algorithm, approximately 50 percent of erosions are going to require surgical management. I would say that would be in the same ballpark for the other complications of pain and dyspareunia.
Q. I'm going to jump back to something. I think I've cleaned it up enough for you.

MR. WALDENBERGER: I didn't like the sound of that, Paul, I'm just going to tell you. We were doing well for such a long time. Don't make me regret it. Go for it.

BY MR. ROSENBLATT:

Q. Do you agree that it would be preferable to have less mesh instead of more mesh?

A. Preferable --

MR. WALDENBERGER: Hold on a second. Object to the form, asked and answered. The only thing different is you are using the word "preferable" as opposed to "safer" or "more beneficial." With that being said, I will allow him to answer the question yet one more time. Go for it.

A. Preferable for the areas where the mesh is not.

Q. And if you had to choose, hypothetically, with all things remaining equal, and we are talking complications, efficacy, will you agree that it would be preferable to have a sling with less mesh as opposed to more mesh?

MR. WALDENBERGER: Objection, asked and answered. You can answer again.

A. Preferable for where the sling is not.

Q. I now want to turn to Page 16 of the report and towards the bottom of the first paragraph you say, "In 2011, Dr. Neuman published his findings that the TVT caused significantly more dyspareunia than the TVT-O due to the stiffness/rigidity of the mesh."

Did I read that correctly?

A. Correct.

Q. And that would be the paper by Neuman titled "Transobturator vs. Single-Incision Suburethral Mini-Slings with 3-Year Followup?

A. Correct.

(Rosenzweig Exhibits 7 through 13 were marked for identification as of 2/4/16.)

BY MR. ROSENBLATT:

Q. I have gone ahead and premarked a number of exhibits here. I will go ahead and hand them to you all at once. These will be Exhibits 7 through 13.

MR. WALDENBERGER: Great. Thank you. You brought a lot of paper with you.

MR. ROSENBLATT: I left half of it

behind.

BY MR. ROSENBLATT:

Q. Okay. Do you recognize what I have handed you as Exhibit 7?

A. Yes.

Q. This would be the Neuman paper that you cited for the proposition that TVT Secur causes more dyspareunia than TVT-O?

A. Yes.

Q. You would agree with me TVT Secur caused significantly lower vaginal and thigh pain than TVT-O, correct?

A. Yes.

Q. And you would agree that it would be preferable to have less postoperative vaginal and thigh pain?

MR. WALDENBERGER: Objection to the form. You can answer.

A. Based on the results of this study.

Q. Yes?

A. Based on the results of this study.

Q. And you find this study to be reliable --

A. Yes.

Q. -- and authoritative?

A. Yes.

Q. And this is the type of study that surgeons in your field would review on a regular basis?

A. Yes.

Q. Is this the type of information that you would use to help counsel patients about either the TVT-O or the TVT Secur?

A. I would not counsel patients on the TVT-O or the TVT Secur.

Q. This is the type of paper that surgeons in your field would use to help them counsel patients about the risks and benefits of TVT-O and TVT Secur?

MR. WALDENBERGER: Objection to form.

You can answer.

A. Doctors would not be counseling patients on TVT Secur currently.

Q. When this was published in 2011?

A. Correct.

Q. And if you look at the conclusion on the first page, it says, "Both the procedures were effective with few adverse events." Did I read

that correctly?

A. That's what the paper states.

Q. And do you disagree with that conclusion?

A. They showed a 31 percent vaginal pain, 31 percent thigh pain for the TVT-O group and an 8 percent dyspareunia. I would disagree with the few adverse events.

Q. And you disagree with the conclusion that both procedures were effective and had few adverse events because of the high rate of vaginal and thigh pain observed in the TVT-O group?

A. And the 8 percent dyspareunia in the TVT group -- I mean, TVT Secur group.

Q. But you would agree that these authors determined or at least concluded that there were a few adverse effects?

A. That's what they state.

Q. If you turn to the second page, on the first paragraph in the top left towards the end it says, "The TVT Secur procedure is regarded by many, although not by all, as effective with little postoperative pain."

Is that a statement that you agree with?

A. It is a statement that these authors make.

MR. WALDENBERGER: Where was that statement again? I'm sorry. Thank you.

BY MR. ROSENBLATT:

Q. And I understand that the authors made that statement. That's why I just read it. My followup question was do you agree or disagree with that statement.

A. I would disagree that it is regarded by many as effective.

Q. When they say regarded by many, they listed references 11 through 14 there, correct?

A. Correct.

Q. And those would be studies that you would have reviewed, correct?

A. Correct.

Q. Now I want to turn to the next page. I'm going to be in the middle of the paragraph here starting with "significant."

"Significant vaginal and thigh pain with VAS score higher than three occurred more frequently with TVT-O, 32 percent versus 1 percent, than with the TVT Secur procedure, 32 percent

versus zero percent prospectively. Thigh pain was transient and lasted no longer than two weeks."

Do you agree that there was a statistically significant difference in the thigh and vaginal pain seen in this study?

A. That's what the authors found.

Q. And on the right side of the page it says cure rate was 86.9 percent for the TVT-O group and 90.9 percent for the TVT Secur group. Do you see that?

A. Yes.

Q. So at least in this study, which is an RCT following patients at three years, these authors concluded that the cure rate for TVT Secur was 90.9 percent; is that correct?

A. This is not an RCT. The study was an open, prospective, non-randomized, two-arm trial, Page 770 under "Methods."

Q. But you would agree in this two-armed comparative prospective study comparing the TVT-O to the TVT Secur, that these authors found at three years the cure rate for TVT Secur was 90.9 percent?

A. That's what they described.

Q. You found this paper to be reliable?

A. Yes.

Q. And this paper you cited again for the proposition that dyspareunia was higher in the TVT Secur group than in the TVT-O group, right?

A. That dyspareunia was higher in the TVT secured group, yes, 8 percent versus zero percent.

Q. And as you just pointed out, this was not a randomized controlled trial, correct?

A. Correct.

Q. And if you look over at Table 4 on Page 772, if you look towards the bottom there, it says postoperative dyspareunia, zero for TVT-O and five patients or 7.9 percent for TVT Secur, correct?

A. Correct.

Q. And so one thing that's important when considering, for example, dyspareunia rates is the total number of patients, correct?

A. Correct.

Q. And at least in this study, this comparative, prospective, non-RCT study, there were five patients who had dyspareunia, correct?

A. Correct, but we do not know the number of patients that were sexually active.

Q. And if you look at Table 3, towards the

bottom left it says, "Vaginal mesh protrusion. TVT-O, 1 patient or 1.4 percent, and TVT Secur, zero, correct?

A. Correct.

Q. How do you explain the zero percent mesh protrusion rate for TVT Secur in this study?

MR. WALDENBERGER: Objection to the form. You can answer.

A. As I described in my report, Dr. Neuman early on described a larger incision and a deeper dissection that would avoid mucosal plication which might lead to vaginal wall penetration.

Q. So it would be fair to say that one of the contributing factors of a mesh erosion or exposure is surgical technique?

A. For the TVT Secur, yes.

Q. Would that be different for the other TVT products?

A. It is specific for the TVT Secur, yes.

Q. So, as I understand your opinion, surgical technique can have -- strike that.

As I understand your opinion, surgical technique could potentially be a factor in contributing to mesh exposures with TVT Secur?

A. Yes, because of what I described in my report.

Q. But that same logic would not carry over to the other TVT products?

A. Because the TVT Secur device, the -- you can't really even call them trocars. The arrow tip of the introducer are different from the other TVT devices.

Q. Is a zero percent --

A. It is, as described by Dr. Robinson, a sling unto itself.

Q. Would you consider a zero percent mesh protrusion rate an acceptable rate?

A. Zero is an acceptable number.

Q. Would you consider a 2 percent mesh exposure rate to be acceptable?

A. I would find it very difficult to state what would be an acceptable rate over zero.

Q. And that's you, Dr. Rosenzweig?

A. Correct.

Q. So, you are not speaking for what other surgeons might find to be acceptable or not acceptable with respect to the frequency of mesh exposures?

A. I'm speaking for what I would find unacceptable, yes.

Q. And going back to the Neuman study, on the right side of Page 772 it says, "Common complications of former retropubic operations for treatment of SUI such as pelvic and abdominal organ injury and bladder penetration are rare with the use of TVT-O and TVT Secur because the tape introducers do not cross the retropubic area."

Did I read that correctly?

A. Yes.

Q. Did you agree with that?

A. The tape does not cross the retropubic area with the TVT obturator. The TVT Secur is placed in a "U" fashion and is placed past the urogenital diaphragm. It would enter the retropubic space.

Q. Do you agree with these authors that pelvic and abdominal organ injury and bladder penetration are rare with TVT Secur?

A. In my report, according to the Cochrane analysis done in 2014, adverse event profile is noted to be significantly worse, consisting of a higher rate of operative blood loss, mesh exposure

and bladder and urethral erosion.

Q. So, you disagree with these authors, correct?

A. I'm describing what the Cochrane analysis stated, that there is a increased risk of bladder and urethral erosion.

Q. But you didn't cite the Cochrane analysis for the difference between dyspareunia rates for TVT Secur versus TVT-O, did you?

A. In my report, no.

Q. And if you look at the last paragraph on Page 772, it says "Operative time, the need for concomitant colporrhaphy and early and late postoperative complications were similar in the two study groups."

Do you see that?

A. Yes.

Q. Do you agree or disagree with these authors' findings in this study?

A. The operative time was similar. The need for a colporrhaphy just shows that the groups had a similar amount of prolapse.

Q. But when they say late postoperative complications were similar between TVT-O and TVT

Secur, do you agree or disagree with that statement?

A. Well, what they do is they describe that there was less early postoperative vaginal pain and early thigh pain. However, the dyspareunia, which would be somewhat later in occurrence because there is a certain period of time where you are going to have the patient abstain from vaginal intercourse, that would be a later occurrence.

They also describe that patients that had dyspareunia more often needed a surgical repair for their dyspareunia. So, I would say that there would be more of a later complication associated with the TVT Secur.

Q. So, as I understand your testimony, you wouldn't consider the postoperative vaginal and groin pain seen in the TVT-O group as being a late or long-term complication, correct?

A. Well, I think you've read earlier that that resolved within the first two weeks.

Q. And do you share that same understanding?

A. From this study?

Q. Just in general. Would you consider

that would be accurate?

A. They are describing their data. Now, we do know from other studies, including the Petri study, that for midurethral slings the majority of complications showed up after one year. Only 20 percent of midurethral sling complications show up within the first year, 60 percent show up within years 1 to 3.

Q. And this was a three-year study?

A. Correct.

Q. So, there are some complication rates that are reported in this three-year study that you agree with and there are some that you disagree with as far as being representative of average complications?

A. I would disagree that their zero -- zero percent erosion rate is representative of average complications.

Q. You can put that aside. Pull up Exhibit 8, which is the Hota 2012 study. And that's H-o-t-a.

A. Yes.

Q. And Doctor, I believe you cited the Hota study for the proposition of TVT Secur having

inferior cure rates compared to TVT and TVT-O. Is that accurate.

A. Yes.

Q. And you also mentioned earlier that this was the study that showed a 19 percent mesh exposure with TVT Secur, correct?

A. Yes.

Q. And that you were not aware as you sit here today of a study showing a higher rate of mesh exposure with TVT Secur other than this study, correct?

A. Not that I specifically recall.

Q. And if you look towards the bottom of the first page, it says, "Financial support for this study was obtained from Ethicon Women's Health and Urology, a Division of Ethicon, Inc., a Johnson & Johnson company, as an investigator-initiated study."

Do you see that?

A. Correct.

Q. And would you agree although there is a potential for bias because of the financial support, that does not mean that the study is biased?

A. Correct.

Q. And how did you go about discounting any type of potential bias based on this financial support when you were using this data to cite in your expert report?

A. Again, I looked at the methods. They received institutional review board approval. They did a non-blinded randomized trial. They did a adequate power analysis to determine what the sample size that they would need. They did an equivalent randomization. They described their methodology. They used multiple questionnaires to look at patient symptomatology, so that I found that the methodology used was very -- was exceptional in the study.

Q. So in addition to the methodology being exceptional in this study, you would consider this study authoritative --

A. Yes.

Q. -- and reliable?

A. Yes.

Q. And surgeons in the field would rely on such studies?

A. Yes.

Q. And this was published in the Female Pelvic Medicine and Reconstructive Surgery Journal?

A. Yes.

Q. Am I correct that you are still not FPMRS certified?

A. Correct.

Q. You have no intention of sitting for that certification?

A. Correct.

Q. Do you believe that there is a benefit for surgeons to obtain Female Pelvic Medicine Reconstructive Surgery certification?

A. Someone that is currently in fellowship, yes, because there are much more -- it's a much more rigorous approval process. So, you have to do a fellowship, you have to do a written exam, you have to do a thesis, you have to take a subspecialty oral exam. So, it is a much more rigorous certification process than what was available from 2012 to 2015 for the, quote-unquote, senior circuit. They just need to take a written exam.

Q. And you have not taken any exam to become certified, correct?

A. Correct.

Q. Now, looking at this study, towards the bottom of the results section it says both TVT-S -- which would be TVT Secur, correct?

A. Yes.

Q. So, both TVT-S and TVT-O resulted in improved quality of life and symptoms at 12 weeks. Did I read that correctly?

A. Yes.

Q. There was no difference between the groups for PFDI-20 or PFIQ-7. A similar pattern was seen at one year.

Did I read that correctly?

A. Yes.

Q. And again, you said that you were impressed with the methodology of this study?

A. Yes.

Q. And so what this study showed is at one year, when comparing TVT-O to TVT Secur, that there was no statistically significant difference in the quality of life between the two, correct?

A. No. There was no difference in the change in the quality of life or the difference in the surveys between the two.

Q. But you would agree that both TVT Secur and TVT-O resulted in improved quality of life in symptoms for these patients?

A. Based on the symptom questionnaires that were done.

Q. And those are validated and reliable questionnaires?

A. Those are validated and reliable questionnaires. I would suggest that someone that had a -- that they found a 19 percent erosion rate and a 19 percent subsequent reoperation rate and a 50 percent objective stress incontinence rate or, excuse me, 55 percent objective stress incontinence rate would state that there probably would be a lower degree of improvement of quality of life for the TVT Secur.

Q. Now I'm over on the right-hand column starting with "midurethral." "Midurethral tension-free slings are minimally invasive procedures that have been shown to have high success rates and low overall complication rates."

Did I read that correctly?

A. And you are on which page now?

Q. First page.

MR. WALDENBERGER: Second paragraph. What was the sentence again?

MR. ROSENBLATT: First sentence.

MR. WALDENBERGER: Got it.

A. That's what they state.

Q. And do you agree or disagree with that statement?

A. Minimally invasive -- excuse me. "Midurethral tension-free slings are minimally invasive procedures that have a high success rate and how complication rate"?

Q. Yes.

A. I disagree with that, yes.

Q. And towards the bottom starting with "In an attempt," it states, "In an attempt to further minimize postoperative complications and reduce the need for anesthesia, single-incision slings have been developed such as TVT Secur." Correct? Did I read that correctly?

A. Yes, you did.

Q. You would agree that that is a noble thing for surgeons and manufacturers to try to achieve?

A. They state in an attempt, in an attempt

to minimize postoperative complications and reduce the need for anesthesia. That's what the attempt was.

Q. But that would be a good thing, correct?

A. To try to attempt that?

Q. I'm asking you.

MR. WALDENBERGER: I guess he is not understanding your question, if I'm understanding what you are asking him.

A. Again, I'm not understanding the question.

MR. WALDENBERGER: Restate it.

MR. ROSENBLATT: I will strike that.

BY MR. ROSENBLATT:

Q. "Limited data are available with regard to this approach that mirrors the transobturator sling but requires less dissection, uses a smaller amount of mesh and has no exit sites for the mesh. Early studies indicate a range of objective cure rates from 70.3 percent to 87.5 percent."

Did I read that correctly?

A. Yes, you did.

Q. And do you disagree with those findings?

A. Well, we know from my report that the

incision size needed to be larger, the depth of dissection needed to be increased in order to attempt to minimize blood loss, minimize erosions and minimize operative complications.

Q. And if you turn to the bottom right-hand page, it says Page 43, I'm looking at Table 3, it says, pain on postoperative day 7, TVT Secur, zero; TVT-O, one. Do you see that?

A. Yes.

Q. And that was statistically significant?

A. Yes.

Q. And you agree there are some patients who would prefer to have less postoperative pain after a surgical procedure for stress urinary incontinence?

MR. WALDENBERGER: Objection to form.

You can answer.

A. Yes.

Q. And then if we go down, length of catheterization for TVT Secur, zero, and for TVT-O, zero. And you agree that it's a benefit for some patients to not have to leave the operation with the catheter, correct?

A. Correct.

Q. And then it says mesh exposure, 8 patients" -- strike that.

It says mesh exposure, 8 patients or 19.1 percent for TVT Secur and zero patients or zero percent for TVT-O, correct?

A. Correct.

Q. What is your explanation for the zero percent mesh exposure for TVT-O?

A. In the one-year followup there were no patients that presented with an exposure with the TVT obturator.

Q. Based on the study are you able to determine why zero patients experienced a mesh exposure in the TVT-O group?

MR. WALDENBERGER: Objection to the form. You can answer.

MR. ROSENBLATT: I hope this pause isn't cutting into my time.

MR. WALDENBERGER: I'm not tracking the pause, but I won't hold it against you.

A. The authors theorize that the increase in the incidence of mesh exposure in the TVT Secur group is due to the sharp edges of the TVT Secur introducer potentially creating more trauma to the

vaginal epithelium and results in a higher erosion rate.

Q. Did I hear you correctly that they say theorize?

A. Correct.

Q. And so what that means is that they don't know but they are essentially guessing?

MR. WALDENBERGER: Objection to the form. You can answer.

A. No. But they noted that there are sharper edges for the TVT Secur. We know that sharper edges will cause more tissue drag as described in my report and lead to more damage to the vaginal tissue, increasing the risk of exposure.

Q. What clinical studies are you basing that on?

A. What clinical studies?

Q. What clinical studies support what you just mentioned?

A. Well, this clinical study is one of them.

Q. And in this clinical study these authors said that they were theorizing that the sharper

edges could potentially create more trauma, correct?

A. Well, they document the sharp edges.

Q. Right, but the answer to my question is they theorize that it could potentially create more trauma, correct?

MR. WALDENBERGER: Objection, asked and answered. You can answer it again, if you understand what he is asking you.

A. They do say they theorize. They do say they theorize, they do state we theorize and potentially create more trauma, but they do document the sharp edges.

Q. Thank you, Doctor. So, as I understand it, in this study these authors suggest a theory to explain the 19 percent or the 5 patients who had a mesh exposure in this study, but my original question to you was --

A. There were eight patients.

Q. Eight patients. I'm sorry. Thank you for correcting me. But my question was, how do you explain the zero percent mesh exposure for the TVT-O group?

MR. WALDENBERGER: Objection, asked

and answered. You can answer it again.

And Paul, are you asking him for his interpretation or you are asking him to point out in the article to you what their basis for zero was?

MR. ROSENBLATT: I'm just asking as a surgeon who uses this study as support for his opinions how he explains the zero percent mesh exposure for TVT-O, and I understand his rationale for why the 19 percent might be there for TVT Secur, but now I'm asking about the TVT-O.

MR. WALDENBERGER: You can answer.

A. That is not discussed this in report.

Q. Do you have an opinion one way or the other as to how these authors were able to obtain a zero percent mesh exposure rate for TVT-O in this study?

A. Not how these authors specifically were able to obtain a zero percent erosion rate.

Q. And if you were to rank levels of evidence using the scientific method, how would you rank hypothesis, theory, testing and conclusion?

A. Well, you start with the hypothesis, you

test it and then you draw a conclusion.

Q. Would you agree that theory would need to be subsequently proven in randomized controlled trials?

A. Well, this is a randomized control trial, and they felt that the sharp edges associated with the Secur was what they attributed their high erosion rate to.

Q. But are you aware if they followed up with additional testing to confirm that hypothesis or theory?

A. Not that I'm aware of.

Q. And they attribute the laser-cut edge of the TVT Secur to the higher exposure rate, but how do you explain the lack of dyspareunia or postoperative pain in the TVT Secur group?

A. Dyspareunia is not described in this report. They describe their findings from the cumulative results of the quality of life questionnaires that were performed.

Q. And these authors indicate towards the bottom of Page 43, "The lower overall success of TVT Secur could be attributed to the difficulty that sometimes was encountered in the detachment of

the introducer from the sling. During the introducer removal process, the original tensioning may have been compromised as the introducer was moved back and forth in an attempt to release the sling from the introducer."

Did I read that correctly?

A. Yes.

Q. So, is it your understanding that you would attribute the failure rate in this study to surgeon technique?

MR. WALDENBERGER: That he would attribute to it?

MR. ROSENBLATT: Yeah, from reviewing this study.

MR. WALDENBERGER: He is asking your opinion.

A. Right. No, I deal with that in my report. That is a design defect of the TVT Secur, difficulty in removing, releasing the Ethisorb fleece end and detaching and removing the introducer.

Q. But you are aware of some surgeons not having that difficulty, correct?

A. Correct.

Q. And so this study attributes the lower success rate to surgical technique, correct?

A. No. They attribute it to the design defect of the TVT Secur as I describe it in my report.

Q. Turn to Page 44. In the right column it says, "Minimally invasive midurethral slings have become the primary choice of many surgeons in the treatment of SUI given their high long-term success rates when compared with traditional pubovaginal slings and Burch colposuspension."

Did I read that correctly?

A. You read that correctly.

Q. Do you disagree with the statement that the authors made there?

MR. WALDENBERGER: There is a few statements there. Do you have one in particular?

MR. ROSENBLATT: Sure. Let's break it down.

BY MR. ROSENBLATT:

Q. Do you agree or disagree with the authors when they state that minimally invasive midurethral slings have become the primary choice

of many surgeons in the treatment of SUI?

A. That's what they state.

Q. I'm asking do you agree or disagree with those -- with that statement?

A. I think we have discussed that in numerous depositions.

Q. Do you disagree with that statement?

A. I think we've discussed that the -- you know, the number of surgeons that are using midurethral slings in previous depositions.

Q. Would you agree that there were a significant number of surgeons who were using single-incision slings such as TVT Secur?

MR. WALDENBERGER: Objection to the form, that "significant" is a vague term. You can answer, if you can answer.

A. There are surgeons that use single-incision slings to treat stress urinary incontinence.

Q. And that's true today, correct?

A. There are surgeons that are using single-incision slings under study protocols because there is a 522 order to show safety and efficacy of single-incision slings.

Q. I want to turn to Exhibit 9, which is the Cornu study, and I believe you cited this study for the proposition in your report that TVT Secur does not seem to be an appropriate option for first-line management of SUI in women?

A. That's what the authors state. Therefore, TVT Secur does not seem to be appropriate for SUI first-line management in women.

Q. And was this study a randomized controlled trial?

A. No.

Q. Was this study a long-term study?

A. The mean followup was 30 months or almost three years.

Q. And you would agree that in a number of studies for the Burch colposuspension and the autologous fascial sling the authors combined their cure rates with their improved rates to come to an overall objective cure rate, correct?

A. Yes. And to go back to your previous question, midurethral slings, Burch, in the prospective randomized long-term trials, there was no difference -- in the three 5-year studies there was no difference in cure rate between Burch and

midurethral slings.

Q. I'm going to try not to re-cover too much old ground, so I will keep my lips shut on that one.

A. You had asked that question previously, and I just wanted to be responsive.

Q. And if you look at this study, they showed that 18 patients or 40 percent were cured while 8 patients or 18 percent were improved, correct?

A. Correct.

Q. And so if you add those together, that's a 68 percent cured/improved rate?

A. 58 percent.

Q. I'm sorry. 58 percent?

A. Yes.

Q. Now if you would turn to the next page, Page 158. First of all, Doctor, would you agree that this study is authoritative and reliable?

A. Yes.

Q. And surgeons in your field would rely on such studies?

A. Yes.

Q. Now, at the paragraph starting with "SUI

management," the second paragraph down, "Placement of a suburethral sling is the gold standard for the management of SUI associated with urethral hypermobility. TVT and transobturator tape (TOT) are widely used in this indication with a high success rate and few complications."

Did I read that correctly?

A. Yes.

Q. Do you disagree with the author's statement there that suburethral slings are the gold standard?

A. Yes.

Q. What do you consider to be the current gold standard for the treatment of stress urinary incontinence --

A. There have been a number of --

Q. -- the surgical treatment of stress urinary incontinence?

A. There have been a number of articles that have been written about the term "the gold standard" and the lack of meaning that that term has.

Q. Doctor, would you consider --

MR. WALDENBERGER: Hold on a second.

Were you done answering?

THE WITNESS: Yes.

MR. WALDENBERGER: Okay.

BY MR. ROSENBLATT:

Q. So, Doctor, you would not use the term "gold standard" to describe the Burch colposuspension, correct?

A. I would not use "gold standard" to describe any procedure.

Q. Especially not the Burch colposuspension?

MR. WALDENBERGER: Objection to the form. He answered that with his previous answer. So, you can answer it again.

A. Well, that is the procedure that I perform for my patients with primary stress urinary incontinence.

Q. Doctor, how many Burch procedures have you performed in 2016?

A. Four.

Q. And if you look at Page 159 --

MR. CAMPBELL: I will step out.

(Mr. Campbell left the deposition room.)

BY MR. ROSENBLATT:

Q. -- under "Discussion," at the bottom of that first paragraph it says, "TVT Secur minimizes operative dissection and risk of injury of periurethral elements in pelvic organs as well as the risk of nerve or adductor muscle damage."

Did I read that correctly?

A. Yes, you read that correctly.

Q. And do you agree with that statement the authors made?

A. As I describe in my report, the incision site needs to be at least two centimeters with a deep dissection in order to avoid dragging of periurethral and perivaginal tissue to decrease the risk of erosion.

There is the Anders Hamer paper and also the Cochrane analysis that shows a higher risk of urethral and bladder erosion associated with the TVT Secur which are periurethral elements and pelvic damage. I would agree that the TVT Secur does not go into the adductor muscles.

Q. Doctor, the last paragraph on this page says, "Data analysis shows two different patterns of failure. The first is a primary failure,

diagnosed at the first postoperative visit (13 percent of our cases). This kind of event is well-known by all practitioners in the field of sling surgery and is usually related to the technical failure (sling misplacement), failure of the device itself, bad patient selection, learning curve."

Did I read that correctly?

A. Yes.

Q. Do you agree with the authors that failure of a sling procedure is well-known by all practitioners --

MR. WALDENBERGER: Objection to form, I'm sorry.

Q. -- in your field?

MR. WALDENBERGER: Objection to form.

A. Yes.

Q. Then it goes on to say, "However, all procedures were led by an experienced surgeon and no erosion or sling misplacement was demonstrated."

Did I read that correctly?

A. Yes.

Q. What is your explanation for these authors determining that there were no erosions in

this study?

A. What is my --

MR. WALDENBERGER: I object to the form. Why don't you ask it again. I think we are both kind of confused by that one. Maybe we will read it back.

MR. ROSENBLATT: I will take care of it.

BY MR. ROSENBLATT:

Q. These authors in this TVT Secur study found zero erosions, correct?

A. Yes.

Q. What is your understanding as to how these authors could experience zero percent erosions in this study group?

A. They did not find an erosion in the three years that they were following these patients on average.

Q. And then under conclusions it says, "Our midterm experience evaluating TVT Secur for SUI in women shows that this new technique is safe and quick and is associated with limited and mild side effects."

Do you see that?

A. That's what they state, yes.
Q. Did you disagree with the author's conclusions that TVT Secur is a safe and quick operation?
A. Safe, no. Quick, yes. I agree with quick. I don't agree with safe.
Q. And what is your understanding of how quick the procedure is on average?
A. I think they describe, most authors describe their operative time as less than 20 minutes.
Q. Now, if we go to Exhibit 10, this is the Maslow study?
A. Yes.
Q. And I believe you also cited this in your report for the proposition that TVT Secur has higher failure rates than TVT and TVT-O?
A. Yes.
Q. And this study was comparing TVT Secur to TVT-O?
A. Yes.
Q. And the cure rates in this study at one year for the TVT-O were 86 percent and for TVT Secur 63 percent?

A. Correct.

Q. And the results showed quality of life scores through questionnaires improved in both groups and were not statistically significant, correct?

A. Yes.

MR. WALDENBERGER: Actually, it says different, but okay. So you did not read that one correctly.

MR. ROSENBLATT: I was just asking him.

MR. WALDENBERGER: Okay.

BY MR. ROSENBLATT:

Q. And it also says, "Initial postoperative groin pain was more prevalent in the TVT-O group. However, this resolved quickly with time."

Did I read that correctly?

A. Yes.

Q. And do you disagree with their finding that postoperative groin pain resolves quickly with time after a TVT-O procedure?

A. Do I disagree with their findings?

Q. Yes.

A. That's what they found.

Q. Is that consistent with your understanding of the body of literature on TVT-O?

A. No. There is a group of patients who have long-term, persistent groin pain associated with TVT-O.

Q. So you certainly wouldn't hold this paper out to support the statement that postoperative groin pain quickly resolved with time after a TVT-O procedure, correct?

A. The groin pain that they found in this study resolved quickly.

Q. And you would agree that stress urinary incontinence can have a significant impact on the quality of life of women?

A. In some women, yes.

Q. Would you agree that minimally invasive midurethral sling procedures have revolutionized the treatment of stress urinary incontinence?

A. I would disagree with that.

Q. Would you consider this paper reliable and authoritative?

A. Yes.

Q. And surgeons in your field would rely on such studies?

A. Yes.
Q. And there are two different types of techniques for the TVT Secur, correct?
A. Yes.
Q. And one would be the "U" which would follow the retropubic approach?
A. Yes.
Q. Even a the other would be the "H" or hammock, which would follow the obturator approach without going through the adductor muscles?
A. Yes.
Q. And this study evaluated the TVT hammock approach, correct?
A. Yes.
Q. And what this study showed was that dyspareunia at one year was present in 14.3 percent of patients with TVT-O compared with 6.3 percent of those with TVT Secur, correct?
A. Yes.
Q. And so at least in this study, these authors found a higher rate of dyspareunia in TVT-O than they did with TVT Secur, correct?
A. Yes.
Q. And do you have any understanding as to

why the patients in this study would have a lower dyspareunia rate in the TVT Secur group?

A. That's what these authors found.

Q. Other than their findings, you don't have an understanding as to why that might be, correct?

A. They did not describe that in their report.

Q. And if you look at postoperative groin pain on Table 2, for TVT-O it shows 6 percent and for TVT Secur it shows zero, correct?

A. Can you repeat the question?

Q. Right. I'm on Table 2 --

A. Yes.

Q. -- looking at the presence of groin discomfort?

A. Yes.

Q. And in TVT-O it was present in 6 percent of the patients?

A. Yes.

Q. And in TVT Secur it was zero?

A. Yes.

Q. And vaginal erosion was zero percent in the TVT-O group, correct?

A. Yes.

Q. And one patient or 2.1 percent in the TVT Secur group, correct?

A. Yes.

Q. And so you certainly wouldn't hold this paper out as reliable authority that the vaginal erosion rate for TVT Secur is 2.1 percent, would you?

A. That's what the authors found in this study.

Q. In the interest of time we are going to skip over Exhibit 11.

If you could look at Exhibit 12, which is the Mostafa study?

MR. WALDENBERGER: What did you have as 11?

THE WITNESS: He has it.

BY MR. ROSENBLATT:

Q. And this is a meta-analysis that looked at 26 RCTs involving 3,308 women, correct?

A. Yes.

Q. And at least 12 of those randomized control trials evaluated TVT Secur, correct?

A. Yes.

Q. And if you look on Page 408 on the right-hand column, it says, "All RCTs reported improvement in QOL." That would be quality of life?

A. Yes.

Q. So it says, "Nevertheless, all RCTs reported improvement in quality of life scores at the followup compared with baseline with no significant differences between SIMS versus SMUS."

So is it your understanding there were no differences between single-incision mini-slings versus full-length mini-slings or full-length slings?

A. When the data from TVT Secur was omitted, yes.

Q. And are you suggesting that that statement is based on TVT Secur being excluded?

A. Yes.

Q. And on Page 415 at the bottom right they state, "All currently available single-incision mini-slings share the same type of material, type 1 polypropylene, and the insertion technique through a single vaginal incision; however, they differ in the type/robustness of the anchorage mechanism

used."

Did I read that correctly?

A. You read that correctly, yes.

Q. Would you agree that this study did not evaluate any partially absorbable slings of any type?

A. Correct.

Q. Would you agree from a safety perspective that it would be preferable to have an absorbable fixation tip as opposed to a permanent fixation tip?

A. From what perspective?

Q. Safety.

A. If it was shown that an absorbable fixation tip had a greater safety profile, then it would be safer to have an absorbable fixation tip.

Q. On Page 423 towards the bottom left of the page these authors state, "Interestingly, despite the exclusion of TVT Secur, single-incision mini-slings still had a trend, albeit insignificant, towards higher rates of repeat continence surgery."

Did I read that correctly?

MR. WALDENBERGER: Where was that

again? I'm sorry.

MR. ROSENBLATT: Bottom left, not the last paragraph but up a little bit.

MR. WALDENBERGER: "Unlike other"?

MR. ROSENBLATT: Yes, the bottom of that paragraph.

MR. WALDENBERGER: "The failure to show"? I'm sorry. Could you just re-ask your question so I know what you are talking about?

THE WITNESS: It is right here.

MR. WALDENBERGER: Got it.

BY THE WITNESS:

A. Yes.

BY MR. ROSENBLATT:

Q. So would you agree that these authors indicated a trend towards higher reoperation rates for mini-slings compared to full-length slings?

A. Yes.

Q. If you could look at Exhibit 13, which this is the Nambiar Cochrane review which you cited in your report?

A. Yes.

Q. This Cochrane review analyzed 31 trials involving 3,291 women, correct?

A. Yes.

Q. And it analyzed a variety of many slings, including TVT Secur, MiniArc, Ajust, Needless, Ophira, tissue fixation systems and CureMesh, correct?

A. Yes.

Q. And one thing that these authors concluded was that significant difference in fixation mechanisms may influence outcomes?

A. That's what they describe.

Q. In the studies that we just looked at, Neuman, Hota, Cornu, Maslow, how many of those are cited in this Cochrane review?

And in the interest of time, Doctor, I will just represent to you that the only study I saw was the Hota study.

A. Yeah, I didn't see Neuman being referred to. What was the other one. Maslow?

Q. Maslow and Cornu.

A. Well, Maslow might have come out too late for this 2014 Cochrane analysis, and I wouldn't expect Cornu because it was not a randomized control trial.

Q. So, just because a study doesn't meet

the qualitative criteria for inclusion in a Cochrane review doesn't mean that you wouldn't rely on it for certain purposes to support your opinions, correct?

A. Or to discount my opinions.

Q. Correct?

A. Correct.

Q. And if you turn to Page 18 of this Cochrane review, looking at vaginal mesh exposure, and it shows more women in the single-incision groups had exposure, 6 percent versus 1 percent, and the overall result was statistically significant.

So, would it be fair to say that the average mesh exposure rate for mini-slings would be 6 percent based on this Cochrane review?

A. At this point in time, yes, that's what they described.

Q. At this point in time, this was published in 2014?

A. Yes.

Q. And all of the studies that were included in this analysis for the vaginal mesh exposure were single-incision slings, and they were

all TVT Secur?

A. For this section, yes.

Q. And the authors of this Cochrane review found that to be 6 percent mesh exposure rate for TVT Secur?

A. Based on the studies that they included in their review, yes.

Q. And under "Postoperative pain or discomfort" it states, "The overall result was statistically significant, favoring single-incision slings," correct?

A. That's what they state.

Q. And this Cochrane review is authoritative and reliable, correct?

A. Yes.

Q. And surgeons in your field would rely on such meta-analyses in reviewing complication rates for various procedures?

A. Yes.

Q. And is it your understanding that Cochrane reviews are on the top of the pyramid of evidence-based medicine?

A. They are high up on the pyramid, yes.

Q. And a little further down it says, "The

combined overall result showed that women had less short-term pain or discomfort after a single-incision sling," correct?

A. Yes.

Q. And I think you might have answered this, but I can't recall. You would agree that postoperative -- or reducing postoperative pain would be a benefit, correct?

MR. WALDENBERGER: I object to the form. You can answer.

A. Yes.

Q. And then a little further down it says, "Long-Term Pain or Discomfort." Do you see that section?

A. Yes.

Q. And it says, "This was rare," and when it says "this," they are referring to long-term pain or discomfort?

A. Based on the studies that they looked at.

Q. So the authors conclude that long-term pain or discomfort was rare? Was that a accurate interpretation?

A. That's what they describe.

Q. "A statistically significant difference favored single-incision slings in the latter case only. Although uncommon, women were significantly less likely to have long-term pain after a single-incision sling than after a transobturator sling and the overall result favored single-incision slings," correct?

A. That's what they state.

Q. And the long-term pain or discomfort rate that they list for mini-slings is 0.5 percent, correct?

A. That's what they describe.

Q. And you would certainly take the position that an average figure for a complication listed in the meta-analysis would be more reliable than the complication rate pulled from one particular study, correct?

A. Meta-analysis pools data and therefore, depending on which studies they looked at, that would give you more robust data than from one single study.

MR. ROSENBLATT: I will take a quick break.

MR. WALDENBERGER: Sure.

(Rosenzweig Exhibits 14 through 20 were marked for identification as of 2/4/16.)

(Recess taken, 1:20 - 1:34 p.m.)

(Mr. Campbell re-entered the deposition room.)

BY MR. ROSENBLATT:

Q. Doctor, we just took a quick break. I am going to hand you what's been marked as Exhibit 14.

A. Yes.

Q. Do you understand this to be the TVT Secur instructions for use?

A. Yes.

Q. I would like you to turn to the -- sorry. Let me back up. When was the first time you reviewed the TVT Secur instructions for use?

A. I don't recall if I saw this book when the product was first being introduced and I was being detailed on it. I think that might have been the first time that I saw it.

Q. You don't recall that?

A. I don't specifically recall.

Q. I'm correct that you have never

implanted a TVT Secur?

A. Correct.

Q. Do you know if you have ever discussed the TVT Secur implantation with any surgeon who has performed the TVT Secur?

A. Not that I specifically recall.

Q. And you have never attended any professional education training of any type on the TVT Secur, correct?

A. I might have been in a grand rounds where it was discussed.

Q. But you don't recall?

A. I don't recall.

Q. You have certainly never attended any professional education that Ethicon sponsored regarding the TVT Secur, correct?

A. Correct.

Q. And if you look at Bates ending in 576, it reads, "This package insert is designed to provide instructions for use of the Gynecare TVT Secur system, including the device and inserters. It is not a comprehensive reference to surgical technique for correcting SUI (stress urinary incontinence). Only physicians trained in the

surgical treatment of stress urinary incontinence should use the product. These instructions are intended for general use of the product. Variations in use may occur in specific procedures due to individual technique in patient anatomy."

Did I read that correctly?

A. Yes.

Q. And would you agree that results -- or strike that.

Would you agree with me that there are -- strike that.

Would you agree with me that procedural differences in technique and patient anatomy can affect both complications and success rates for TVT Secur?

A. Well, as I described in my report, that is one of the defects of the TVT Secur.

Q. And if you turn to Page 22, Bates ending in 589, if you look at the last bullet point under "Adverse Reactions," it reads, "Under-correction or incorrect placement may result in incomplete or no relief from urinary incontinence."

Did I read that correctly?

A. That's what it states.

Q. And is your interpretation of that warning there, that under-correction or not providing enough tensioning could then result in no cure of incontinence?

A. That is one of the defects of the device, yes.

Q. But is that how you understand that warning?

A. That is part of the warning.

Q. Put that away. I would like you to look at what's been marked as Exhibit 15. Are you familiar with Dr. Walters and Dr. Weber?

A. I know Dr. Walters. I have met Dr. Weber in the past.

Q. And would you consider them respected physicians in their field?

A. Yes.

Q. And on the front page of this article it states, "Almost all surgical procedures for stress urinary continence performed today involve placement of a retropubic or transobturator midurethral synthetic sling," correct?

A. That's what they state.

Q. Is that still true today? Or strike

that. This was published in 2012?

A. That's when it was published, yes.

Q. And if you turn the page, they state, "Although Burch colposuspension and the pubovaginal fascial sling procedure are effective for both primary and recurrent SUI, they are more invasive than the midurethral slings, cause more voiding dysfunction and have significantly longer recovery times, making them less attractive for most primary and recurrent cases of SUI."

Did I read that correctly?

A. You read that correctly.

Q. And do you disagree with Dr. Walters and Dr. Weber when they made that statement in this article?

A. Regarding voiding dysfunction, there are certain references that show more voiding dysfunction, certain references show less return to the operating room for obstructed voiding. So, I would disagree with that statement.

Q. Would you disagree that the Burch and autologous sling have significantly longer recovery times than midurethral slings?

A. They have longer recovery times.

Q. And you would agree that a shorter recovery time after an incontinence procedure would be a benefit to patients?

MR. WALDENBERGER: Objection, asked and answered. You can answer it again.

A. We have discussed returning to work as an economic benefit.

Q. And the authors go on to state, "The evolution of SUI surgeries have shifted so far toward midurethral slings that Burch colposuspension and the pubovaginal sling procedure are rarely performed or taught in obstetrics and gynecology or urology residence programs." Correct?

A. That's what they state.

Q. Do you know if the Burch procedure is still taught in residency programs at Rush Hospital?

A. Yes. I teach Burch procedures at the residency program at Rush, and so do the other urogynecologists.

Q. And do you also teach the autologous sling at Rush?

A. Yes.

Q. Do you have any idea what other residency programs across the country are doing?
A. I do not.
Q. And do you know whether or not the -- strike that.
Do you know whether or not any surgeon at Rush Hospital has ever used a TVT Secur?
A. I do not think TVT Secur was available at our hospital.
Q. Do you know one way or the other?
A. I do not think the TVT Secur has ever been available at our hospital.
Q. Pull up Exhibit 16. Do you recognize this study?
A. Yes.
Q. And this is a systematic review performed by the Society of Gynecologic Surgeons, also known as SGS, correct?
A. Yes.
Q. The lead author is Schimpf?
A. Yes.
Q. And this is on your reliance list, correct?
A. Yes.

Q. And this is the type of systematic review or meta-analysis that you would consider to be authoritative and reliable?

A. Yes.

Q. And this is also the type of systematic review and meta-analysis that you would put at the top of the pyramid of evidence-based medicine?

A. It is high on the pyramid of evidence-based medicine, and we have also discussed this on multiple different occasions.

Q. And certainly surgeons in your field would rely on such meta-analyses?

A. Yes.

Q. Now, Doctor, I know we have been through this before in the past, but what I want to do is focus on the mini-slings.

A. Yes.

Q. If you could, turn to what's listed at the bottom of this as I think 1.e5, Table 1, and I counted up the TVT Secur RCTs that were included in this analysis, and I counted 14 TVT Secur RCTs. Does that appear to be accurate?

A. Yes.

Q. And if you turn to Table 3, what the

authors did here is they accumulated and analyzed studies looking at various complication rates of various incontinence procedures?

A. Yes.

Q. And the first one I want to talk about is estimated blood loss greater than 200 milliliters. Do you see that at the top of Table 3?

A. I went a few pages.

MR. WALDENBERGER: 1.e7.

A. Yes.

Q. And for mini-sling it shows 1.1 percent?

A. Yes.

Q. And when we say 1.1 percent, that column is the summary estimate of incidence?

A. Yes.

Q. And if we look down at hematoma, the mini-sling has an incidence rate of 0.85 percent?

A. Yes.

Q. And that's less than the 1.4 percent for the Burch and the 2.2 percent for the pubovaginal sling, correct?

A. That's what they found.

Q. Do you have any reason to disagree with

these numbers?

A. The rate of transfusion was higher in the mini-sling than Burch, and they don't even discuss the estimated blood loss with the Burch procedure.

Q. And when you said it is higher, the transfusion rate is higher in the mini-sling, the transfusion rate for the mini-sling was 0.51 percent?

A. Yes, and it was zero for Burch.

Q. And if we look at dyspareunia, for mini-sling the incidence rate is 0.74 percent, correct?

A. Yes.

Q. And the pubovaginal sling is 0.99 percent, correct?

A. Yes, and there is no dyspareunia with the Burch procedure.

Q. But you wouldn't necessarily agree with the statement you just made, correct?

A. According to the Schimpf review.

Q. I'm asking you -- so as I understand it, dyspareunia is not listed for the Burch in this review, but that doesn't mean that it just doesn't

exist for the Burch, correct?

A. So, then what you are stating is by that same logic, because dyspareunia as stated with the mini-sling is 0.74 percent, that doesn't mean that the rate of dyspareunia isn't 10 percent like we found before.

Q. Well, I'm just asking you, would you -- and I appreciate your logic there, but you wouldn't suggest that the Burch has a zero percent rate of dyspareunia, would you?

A. It says retropubic slings have a zero percent risk of dyspareunia or have zero percent dyspareunia, so they didn't even have the Burch there, and so therefore, I would say that there was zero percent risk of dyspareunia.

Q. Is it fair to say that you disagree with the incidence rate of the mini-sling, 0.74 percent dyspareunia?

A. I would disagree with that by the same logic that we talked about the Burch procedure.

Q. And the complication of return to operating room for erosion was 1.4 percent in the mini-sling group?

A. That's what they state.

Q. And 1.6 percent in the pubovaginal sling group, correct?
A. And 2.7 percent for the obturator group.
Q. Under mesh exposure it says mini-sling, 2 percent?
A. Yes.
Q. And in fairness, Burch, zero percent, correct?
A. Correct.
Q. Retropubic, 1.4 percent?
A. That's what they state.
Q. Obturator, 2.2 percent?
A. Yes.
Q. Pubovaginal, 5.4 percent?
A. That's what they state.
Q. And you have no reason to disagree with those figures, do you?
A. Based on the studies that they have reviewed.
Q. And wound healing -- or strike that.
Wound infection, mini-sling was 0.31 percent?
A. And there were no wound infections for the Burch.

Q. It actually shows 7 percent for the Burch?

A. Excuse me. Yes.

Q. And 2.6 percent for pubovaginal slings?

A. Yes.

Q. And for urinary tract infections, the mini-sling had an incidence rate of 3.6 percent?

A. Yes.

Q. And that would be lower than pubovaginal sling at 4.2 percent and Burch at 5.9 percent, correct?

A. That's what they state.

Q. And bowel injury shows a 0.74 percent incidence rate for mini-slings into 3.13 incidence rate for the Burch, correct?

A. And that Burch was based on one study which a laparoscopic Burch.

Q. But that's what they report here?

A. Yes.

Q. And for nerve injury, mini-sling shows zero percent?

A. Yes.

Q. For overactive bladder urgency, mini-sling reports 5.4 percent?

A. Yes.
Q. In fairness, Burch shows a 4.3 percent rate?
A. Yes.
Q. And the pubovaginal, 8.6 percent, correct?
A. That's what they state.
Q. And retention lasting longer than six weeks postoperatively, they have a rate of 2.1 percent for the mini-sling, correct? I'm sorry. Less than six weeks.
A. Yes.
Q. And 12 percent for pubovaginal slings?
A. Yes.
Q. 17 percent for the Burch?
A. Yes.
Q. And they also looked at retention lasting longer than six weeks postoperatively, correct?
A. Yes.
Q. And for the mini-sling they reported 3.3 percent incidence rate --
A. Yes.
Q. -- which would be lower than the

pubovaginal sling at 7.5 percent and the Burch at 7.6 percent?

A. Yes, but zero percent of those patients needed to go back to the operating room for urinary retention for the Burch.

Q. And so you are jumping ahead. The next one is return to operating room for urinary retention. As you pointed out, the Burch was zero percent?

A. Yes.

Q. Mini-sling was 1.9 percent?

A. Yes.

Q. The pubovaginal sling was 3 percent?

A. That's what they state.

Q. For groin pain the mini-sling showed 0.62 percent.

A. Yes.

Q. And that's slightly higher than the pubovaginal at 0.34 percent?

A. Yes.

Q. And the Burch showed 1.1 percent?

A. That's what they state.

Q. And for leg pain, these authors conclude that the mini-sling has a 1.6 percent incidence

rate?

A. Yes.

Q. And with the obturator they show a 16 percent incidence rate, correct?

A. Yes.

Q. And with bladder perforation the authors conclude the mini-slings have a 0.85 percent incidence rate?

A. That's what they found.

Q. And that's lower than the pubovaginal at 2.3 percent, the Burch at 2.8 percent and the retropubic at 3.6 percent?

A. Yes.

You didn't want to discuss urethral perforation?

Q. Sure. Urethral perforation, mini-sling, they report 2.7 percent?

A. Yes.

Q. And would you say that that is an accurate number?

A. That was again described in the Cochrane analysis in 2014 that there was a higher bladder and urethral risk associated with the mini-sling.

Q. And here they are showing that that's

based on one study evaluating 37 patients, and out of those, one patient had urethral perforation?

A. That's what they described.

Q. Now, if we turn to 1.e16, in the middle of the page it states, "Exposure of the sling postoperatively is similar with either obturator slings, 2.2 percent, or mini-slings, 2.0 percent, but retropubic slings have a somewhat lower rate than either at 1.4 percent." Correct?

A. That's what they state.

Q. And they go on. Is that consistent with your understanding of what the body of literature shows on average?

A. On average, no.

Q. And what are you relying on to suggest that these figures are not accurate?

A. Regarding the mini-slings in general or the TVT Secur in specific?

Q. TVT Secur.

A. Well, we know from the studies that we looked at and the meta-analysis that we looked at has a higher erosion rate associated with the TVT Secur.

Q. Anything else?

A. What we have discussed earlier and what's in my report.

Q. These authors go on to state in this SGS meta-analysis that dyspareunia is rare with any type of sling but is somewhat more common with a mini-sling at 0.99 percent than either a retropubic at less than .001 percent or a obturator at 0.16 percent, correct?

A. That's what they describe.

Q. And do you have any reason to dispute the findings that the authors concluded in this meta-analysis regarding dyspareunia being there?

A. Specifically for TVT Secur?

Q. Yes.

A. Yes, the information that we have discussed earlier.

Q. And if you look on 1.e18, the top left paragraph, am I correct that the authors of this meta-analysis determined that the TVT Secur was the most widely studied mini-sling?

A. On e18?

Q. Yes.

A. Where are you looking?

Q. "It should be noted that this is the

most widely studied mini-sling," and TVT Secur is referenced on the previous page. Do you see that?

A. Yes.

Q. Is that consistent with your review of the literature?

A. Yes.

Q. You can put that away. Now if you will look at Exhibit 17. Do you recognize this study?

A. Yes.

Q. And this is a study done by the lead author Tincello?

A. Yes.

Q. And it's the TVT Worldwide Observational Registry, correct?

A. Yes.

Q. And this is a study that you have on your reliance list?

A. Correct.

Q. You would consider this study to be authoritative and reliable?

A. Correct.

Q. And surgeons in your field would rely on such studies?

A. Correct.

Q. And what this study shows is at one-year followup, 1,334 women were studied?

A. Not at one-year followup, no.

Q. What are you basing that on?

A. On table -- I think it's Table 1 or Graph 1, where you have the consort analysis of the data, we see that only out of the 677 Secur, the 469 TVT and the 252 TVT-O in the study, for Secur 45 withdrew their consent; 21 of the TVT withdrew their consent; 44 withdrew their consent for the TVT-O.

There were 111 lost to followup for TVT Secur, 92 for TVT and 68 for TVT-O.

Contraction stress test for TVT Secur was slightly higher 50 percent -- excuse me. Cough stress tests were obtained in slightly above 50 percent of patients at 347 for Secur, 187 for TVT, so it's less than 50 percent and also less than 50 percent of one-tenth of TVT-O.

Q. And these results show that there was about an 84.2 percent objective cure rate for TVT Secur?

A. With only 50 percent of patients being followed up with a cough stress test at 12 months.

Q. With that caveat, based on the patients that they were able to follow up, these authors reported about a 84 percent cure rate for TVT Secur?

A. With a 50 percent lost to followup, yes, that's what they report.

Q. And these authors concluded that the TVT Secur cohort had the shortest operative time, the lowest proportion of women who required an overnight stay and the most women who underwent surgery under local anesthesia. The median time -- did I read that correctly?

A. Yes.

Q. They go on to state the median time to return to employment, housework, sex life and hobbies was most rapid for Secur, correct?

A. For the 50 percent of women that returned for followup, yes.

Q. You agree that it would be a benefit to patients to be able to return to employment, housework, their sex lives and hobbies faster?

A. We discussed the economic interest of employment.

Q. Would that apply to sex life as well?

A. That I -- there is no economic benefit for returning to sex life, and I am not sure that my wife would agree that returning to housework is an advantage.

Q. If you look --

MR. WALDENBERGER: Did you want to strike that last part?

Q. Page 2313, the paragraph on the right, it states, starting in the middle of the sentence, "low surgeon experience with fewer than 50 procedures was associated with a lower likelihood of success than surgeon experience with 50 to 99 procedures," correct?

A. That's what they state.

Q. And so what that suggests is that surgeons with more experience and higher volume have better success rates, correct, at least in this study?

A. And that is what is described in my report as one of the defects of the design of the TVT Secur.

Q. But you would agree with me that at least in this study, increased surgeon experience and volume was attributed to better success rates?

A. As described in my report, that is a defect of the TVT Secur.

Q. If you look at Table 2, which lists the complications, it says bleeding greater than 200 milliliters, and for TVT Secur, they report 0.7 percent?

A. Correct.

Q. And for postoperative complications there is sling erosion. Do you see that?

A. Correct.

Q. And if you go across, the numbers are 1.5 percent for TVT, 0.4 percent for TVT-O and 1.2 percent for TVT Secur. Do you see that?

A. Yes, but you can't -- what they are basing those percentages on is the total number of patients, not the total number of patients that came back at 12 months, because you don't know with the 50 percent lost to followup whether or not they had a long-term postoperative complication like sling erosion, groin pain, voiding dysfunction, mixed incontinence, abdominal pain, dyspareunia. So, instead of using the 677 as your denominator you have to use the 374 as your denominator.

Q. That's what these authors concluded

here, correct?

A. That's what these authors concluded.

Q. And for dyspareunia they have zero percent for TVT Secur, correct?

A. That's what they describe.

Q. If you look under the discussion sections, the authors indicate a major advantage of Secur appear to be its potential suitability for an in-office based procedure rather than surgery requiring formal day case hospitalization due to the safety profile, correct?

MR. WALDENBERGER: "Correct" meaning you read it right?

MR. ROSENBLATT: Yes.

MR. WALDENBERGER: Do you see where he read?

A. I'm going back to look at their methods and seeing the number of patients --

Q. Did I read that correctly, Doctor?

A. Yes, you did, but they do not describe in their methods that any of the women actually had the procedure done in the office, so it is difficult for me to agree with the statement that it could be done in the office if they didn't even

study it being done in the office.

Q. And that's a study that was on your reliance list?

A. Correct.

Q. And if you would look at Exhibit 18. Do you recognize this study?

A. Yes.

Q. This is a study by Walsh, which looks at a systematic review of TVT Secur procedures at 12 months in 1,178 women?

A. Yes.

Q. And this would be reliable and authoritative?

A. As far as data in 2011, yes.

Q. And surgeons in your field would rely on such studies?

A. Yes.

Q. And again, a systematic review would be higher on the pyramid of evidence-based medicine?

A. Yes.

Q. And these authors --

A. But that is assuming that this is a systematic review instead of just a literature review.

Q. And these authors indicated that there was a 2.4 percent incidence of mesh exposure in the first year after a TVT Secur?

A. That's what they describe.

Q. These authors also describe a 1 percent dyspareunia rate, correct?

A. That's what they describe.

Q. And the authors also describe a 0.8 percent rate for returning to the theater for complications?

A. That is what they describe.

Q. And these authors conclude that the cure rate, both objective and subjective cure, was 76 percent?

A. That is what they describe.

Q. And they describe that as being similar to more established midurethral slings?

A. That's what they state.

Q. If you would, turn to Page 655, Table 4, which relates to postoperative complications. You see here there are 11 studies listed there?

A. Yes.

Q. And those are all studies evaluating patients who had a TVT Secur?

A. Correct.

Q. And in the next column over they list out the mesh exposure rates for all the patients who were followed up in those studies?

A. Correct.

Q. And that's where we get the total 2.4 percent from, correct?

A. Correct.

Q. And if you look towards the right of the table under pain and dyspareunia, that's where we get the 1 percent from, correct?

A. Correct.

Q. And under the first paragraph of the discussion section the authors indicate "Synthetic midurethral slings are now considered to be the gold standard surgical treatment for women with SUI and have become the benchmark against which new therapeutic interventions must be assessed."

Did I read that correctly?

A. You read that correctly.

Q. And again, what these authors concluded was that success rates and complication rates for mini-slings such as the TVT Secur were similar to full-length slings, correct?

A. That's what they state.

Q. I hand you what's been marked as Exhibit 19. Do you recognize what I have just handed you?

A. Yes.

Q. And Exhibit 19 is the TVT Secur European feedback from May 15th, 2007?

A. Yes.

Q. And if you could, turn to this page that states, "Paris European Expert Meeting: Results from Early Experience."

A. Yes.

Q. And what this shows is a number of physicians here along with their respective countries, correct?

A. Yes.

Q. It also shows the number of patients who they have implanted a TVT Secur in, correct?

A. Yes.

Q. And to the right of that they list the dry rates or the cure rates from their earlier experience with the TVT Secur, correct?

A. Yes.

Q. What this shows is at least these surgeons had cure rates with TVT Secur anywhere

from 87 percent to 100 percent, correct?

A. On Page 1, on the first page, and then the second page it goes down to 50 percent and up to 77 percent.

Q. We will get there, but am I correct that --

A. Yes.

Q. And on the next page we see the cure rates from anywhere from 50 percent to 77 percent?

A. Correct.

Q. And this would suggest that there is a learning curve with the TVT Secur that affects cure rates, correct?

A. As I described in my report, that is a defect associated with the device.

Q. But you would agree with that proposition?

A. Yes. That it is a defect associated with the device, yes.

Q. Okay. You can put that away. I handed you what's been marked as Exhibit 20.

Put this in that bottom portion there.

Do you recognize what I've just handed you as Exhibit 20?

A. Yes.

Q. And is this the TVT Secur Quality Board presentation?

A. Yes.

Q. And if you look on Page 2, what Ethicon realized was that the potential root cause of lower efficacy rates in Germany was attributed to surgeon training, correct?

A. They call it proctor training.

Q. And based on your review of the testimony and documents regarding TVT Secur, is it your understanding that the experiences in Australia and Germany were not consistent with the rest of the world and the United States?

A. No. That it was not consistent. I mean, it was consistent with what was seen in other countries too, not just in Germany and Australia.

Q. So if you go to Page 4. I'm sorry.

Go to Page 9. It describes the German experience. It states that there was a spike in post-procedural incontinence complaints in February of 2007 and investigation determined that the root cause was preceptor-based training which had variable results?

A. That's what they state.

Q. If you go to Page 11, what this slide indicates is Dr. Lucente's cure rates over time evaluating his first 25 patients, his first 77 patients, his first 108 patients, and then it looks at his last 25 patients, correct?

A. That's what this states.

Q. And what this shows is initially Dr. Lucente's cure rates were around 60 percent in his first 25 patients, correct?

A. Yes.

Q. And then as he gained more experience with the TVT Secur, when he looked at the first 77 patients his success rate increased to 68.8 percent?

A. That's what this states.

Q. And as Dr. Lucente gained even more experience and familiarity with the technique of TVT Secur, when looking at 108 patients, it shows that his cure rates jumped up to 72.2 percent, correct?

A. It had increased to 72.2 percent, yes.

Q. And if you just look back at the most recent or the last 25 patients at this time, his

cure rate at that time increased to 84 percent, correct?

A. That's what this states.

Q. Now, I understand you are critical of the learning curve and some of the difficulties around the surgical technique, but as I understand your opinions, you are critical of the failure rates based on -- that are attributable to technique as opposed to the mesh, correct?

MR. WALDENBERGER: Objection to the form, vague; I think mischaracterizes testimony. You can answer.

A. The stiff laser-cut, heavyweight, small-pore mesh increases the risk of poor smooth muscle contractility, which would explain the increased failure rate along with the difficulty in getting the Ethisorb fleece in the appropriate position and dislodgement of the Ethisorb upon removal of the inserter.

Q. If a patient who had a TVT Secur had a mesh exposure, what is your differential diagnosis to determine what the mechanism or the cause of the mesh exposure was?

A. What is on my differential?

Q. Yes.

MR. WALDENBERGER: Assuming what product they had?

MR. ROSENBLATT: TVT Secur.

A. Number one, the stiff mesh. Number two, tissue dragging from a small incision that is not deep enough. The sharp edges of the introducer that is pulling through tissue. Mesh contraction, degradation, chronic foreign body reaction, chronic inflammation.

MR. WALDENBERGER: Slow down.

MR. ROSENBLATT: I know it's exciting.

A. And all the other things I've described in my report.

Q. Are you able to attribute a specific percentage of mesh exposures that are caused due to the stiff mesh?

A. A specific percentage?

Q. Yes.

A. I think all of the things I described contribute to mesh exposure.

Q. So there is no way for you to break out whether a mesh exposure was caused by the stiff mesh, the tissue dragging, the sharp edges, the

contraction or any other factor?

MR. WALDENBERGER: This hypothetical patient we are talking about?

MR. ROSENBLATT: In this hypothetical patient.

MR. WALDENBERGER: Who he has never seen.

A. In a hypothetical patient, without knowing the specifics of the patient's surgical course, postoperative course and other specifics about the patient, I would not be able to opine about which of the mechanisms was more likely the cause, which of the defects of the product were more likely the cause of the mechanism of the injury that she sustained.

MR. ROSENBLATT: Would you mark that.

(Rosenzweig Exhibit 21 was marked for identification as of 2/4/16.)

BY MR. ROSENBLATT:

Q. Doctor, I have handed you what's been marked as Exhibit 21, and the Bates stamp on this is ETH.MESH.00369999.

A. Yes.

Q. Doctor, do you understand this to be a

professional education slide deck for TVT Secur?

A. Yes.

Q. And if you could, turn to -- the pages aren't numbered, but at the top it states "Surgeon feedback for third generation." Are you there?

MR. WALDENBERGER: Past the middle.

MR. ROSENBLATT: About six pages in, seventh page.

MR. WALDENBERGER: Got it.

THE WITNESS: Okay.

BY MR. ROSENBLATT:

Q. And it states, "Surgeon feedback before third generation. Wanted simpler and less invasive techniques to reduce potential complications." Correct?

A. That's what they state.

Q. And they list bullet points there to maximize safety, minimize passage or minimal passage through tissues and less material left behind in the patient, correct?

A. That's what they state.

Q. And you agree based on the slide that there were at least some surgeons who saw a potential benefit of having less material left

behind?

A. That's what this slide states.

Q. And if you look at the next slide, that's showing a TVT Secur in someone's hand, correct?

A. Correct.

Q. And you would agree with me that it is considerably smaller than the full-length slings, correct?

A. Correct.

Q. And if you turn to the next slide, it discusses how the TVT Secur is only eight centimeters long --

A. Correct.

Q. -- and how there are no exit points?

A. That's what they state.

Q. Now, if you will turn to the third-to-the-last page, and this is a snapshot or a table of the TVT Secur abstracts from the IUGA 2007 meeting?

A. Yes.

Q. And so these would have been abstracts that would have been published in the medical literature as well as presented at this

international conference?

A. Yes.

Q. And what this study shows is that when you look at these seven studies evaluating 410 patients, that there was an average subjective cure rate of 85.4 percent?

A. At six weeks, 6.6 weeks, that's what they state.

Q. Put that away. This is 22.

(Rosenzweig Exhibit 22 was marked for identification as of 2/4/16.)

BY MR. ROSENBLATT:

Q. Doctor, do you recognize what I've handed you that has been marked as Exhibit 22?

A. Yes.

Q. And this is a professional education slide deck regarding TVT Secur, Bates number FMESH00308094. This is from July of 2006.

A. Yes.

Q. And I would like you to turn towards the end, about six or seven pages from the end, at the top, "Gynecare TVT Secur System Early Clinical Observations."

A. Yes.

Q. And what this is discussing are just some, I guess, lessons learned or some tips and tricks in this professional education slide deck, correct?

A. Yes.

Q. And if you look at the bottom it says, "Do not retract or pull on mesh while removing inserter. Do not use the Babcock technique," correct?

A. Correct.

Q. And the Babcock technique would essentially be when you put a Babcock or sometimes another surgical instrument such as a helical passer in between the urethra and the mesh, correct?

A. No.

Q. Or you are clamping a little bit of the mesh to prevent or to leave a little tension?

A. The Babcock technique was specifically taught by Dr. DeLaval for the obturator, TVT obturator technique.

Q. And the intent of the Babcock technique was to make sure that the mesh wasn't tensioned too tight, correct?

A. The observation was that it was much more difficult to remove the sleeves with the TVT obturator and therefore, you needed to hold a 2-millimeter knuckle of sling in a Babcock when removing the sheath to avoid putting too much tension on the urethra.

Q. And that's a technique that surgeons employed over time to help facilitate a better mesh placement, correct?

A. Or the TVT obturator.

Q. And what this slide deck is relaying to physicians is that the consequence of using the Babcock technique with the TVT Secur is that the mesh will be too loose, correct?

A. That's what they state.

Q. And it states the implant will not get tighter as with current TVT?

A. Meaning that the mesh contracts.

Q. And so, Doctor, would you agree that a benefit of TVT Secur is that it was difficult to overtension or provide excessive tension?

A. No. As I describe in my report, one of the other tips and tricks was to place this under, quote-unquote, more tension than the TVT. We know

from what doctors around the country, including Dr. Farnsworth, said, that tension-free is a misnomer. It was never tension-free. Dr. Arnaud and Hinoul had that in one of his presentations that we were never tension-free and we will never be tension-free.

So, this was -- the TVT Secur was specifically placed with greater tension than, quote-unquote, the tension-free, which is a misnomer because there is no way to place these tension-free.

Q. And you will agree that surgeons who became familiar and experienced with the tensioning of the TVT Secur had good results?

MR. WALDENBERGER: Objection to form. You can answer. It's vague.

A. With what?

Q. With TVT Secur.

MR. WALDENBERGER: Objection to the extent that "results" is a vague term that you are not relating it to a particular thing. You can answer if you understand.

MR. ROSENBLATT: I will rephrase.

BY MR. ROSENBLATT:

Q. You will agree with me that there were surgeons who were able to refine the technique for TVT Secur, correct?

A. There were surgeons that reported a higher success rate than other surgeons.

Q. And so at least for some surgeons who were able to learn the nuances of the TVT Secur procedure, they had good results as far as high success rates and low complications in some patients, correct?

MR. WALDENBERGER: Objection to form.

You can answer.

A. And there are other doctors who were taught the nuances that could not get a higher success rate and a lower complication rate.

Q. And I understand that. There were some surgeons who were retrained and they still didn't have great results, correct?

A. Correct.

Q. But on the contrary, there were surgeons who were comfortable with the tensioning of the TVT Secur, correct?

A. There are --

MR. WALDENBERGER: Objection to the form. You can answer.

A. There were doctors that reported better success rates.

Q. And so at least for some doctors who were comfortable with the TVT Secur and the surgical technique, they had good patient results?

A. There are doctors that reported better surgical outcomes and higher success rates.

Q. And so for those doctors and those patients, TVT Secur was a good product for them?

MR. WALDENBERGER: Objection to the form. You can answer.

A. I cannot speak to the individual patients.

MR. WALDENBERGER: Or their physicians.

THE WITNESS: Or their physicians.

MR. ROSENBLATT: Go to the witness.

MR. WALDENBERGER: That's the first time after 4 hours and 38 minutes.

MR. ROSENBLATT: You get one. I will tell you what. If you could give me five minutes just to make sure we don't have any

wrap-up questions and we will be out of your hair.

MR. WALDENBERGER: Sure, go for it.

MR. ROSENBLATT: Off the record.

(Recess taken, 2:28 - 2:35 p.m.)

(Mr. Campbell left the deposition proceedings.)

(Rosenzweig Exhibit 23 was marked for identification as of 2/4/16.)

BY MR. ROSENBLATT:

Q. Doctor, we are back from a short break here. Would you agree with me that the issues that were described in Australia that are referenced in your expert report, that they involved problems with efficacy and not safety?

A. The main discussion in Australia was efficacy.

Q. And when you said earlier that the experience in Australia and Germany was consistent with the rest of the world, what are you relying on to make that statement?

A. Internal documents.

Q. Which internal documents are you referring to?

Doctor, I have got one that might refresh your recollection, so...

A. All right.

Q. If you could look at what I've just handed you that has been marked as Exhibit 23. Have you seen this document before?

A. Yes.

Q. And this is the TVT Secur PQI07-041 Quality Board followup, correct?

A. Yes.

Q. And this presentation is essentially an analysis of the efficacy problems observed in Australia and Germany, correct?

A. It's the review of global complaints looked at by region and country.

Q. And so, for example, if you look at Page 4 titled "Global Complaint Review," they look at -- they do Pareto analyses and see that the top global complaint is post-procedure incontinence?

A. Correct.

Q. And post-procedure incontinence is essentially a problem with efficacy or the procedure did not cure incontinence as it was intended to do, correct?

A. Correct.

Q. And failure of a procedure is a recognized complication with any surgery intended to treat stress urinary incontinence, correct?

A. It is, depending on what the rate of post-procedural incontinence is.

Q. And so in this presentation Ethicon is essentially escalating a global complaint review that was essentially based on complaints from three surgeons in Australia, correct?

A. Three surgeons that are very familiar with mesh. In fact, one of the doctors, Dr. Carey, invented the Prosima device, which is a exitless non-fixed, if you will, pelvic organ prolapse device.

Q. And that pelvic organ prolapse device is made out of Gynemesh PS?

A. Correct.

Q. And I assume you do not believe Gynemesh PS would be a safe mesh to use for stress urinary incontinence?

A. It would be less dangerous than the heavyweight small-pore mesh, 100 grams per meter squared, 1-millimeter pore size in the TVT product

line.

Q. And what are you basing that on?

A. The fact that, as I described it during the Abbrevo trial, that Gynemesh PS is less stiff than Gynemesh.

Q. Any clinical studies that you are relying on?

A. No. That's based on internal documents from Ethicon.

Q. But as I understand it, you are not offering the opinion in your expert report that Gynemesh PS is a safer alternative design, correct?

A. I am not offering Gynemesh PS as a safer alternative design.

Q. And am I correct that the safer alternative design that you are suggesting in this case for TVT Secur is the Ultrapro mesh?

A. Correct.

Q. And that's based on the Okulu study?

A. That's one of the studies.

Q. What other clinical studies are you relying on to support your opinion that Ultrapro would be a safer mesh?

A. The studies from the Moalli group that

look at the lighter weight, larger pore mesh.

Q. I'm sorry to cut you off. I'm talking about clinical studies in women.

A. Specifically looking at a partially absorbable mesh?

Q. Yes.

A. And specifically compared to a non-partially absorbable mesh?

Q. I don't care if it's comparing it to anything. I want to know what clinical studies using a partially absorbable mesh, i.e., Ultrapro, that you are relying on to support your opinion.

A. There are -- I don't think that they are on this reliance list, but they might be. There are several studies that have looked at partially absorbable mesh and the efficacy and partially absorbable mesh and the benefit to a non-partially absorbable mesh.

Q. But I'm correct that those are not on your reliance list here? I didn't see them.

A. That I haven't looked at specifically for that.

Q. Am I correct that the only clinical studies evaluating Ultrapro as a sling in women is

the Okulu study?

A. Correct.

Q. And you are not aware of any other studies evaluating Ultrapro as a sling in women?

A. Not that I'm aware of.

Q. I want to go back to Page 7 of this slide deck, and again, this presentation is summarizing the results of the global complaint review, and this slide shows ROW, which can we agree urethra that stands for rest of the world?

A. Yes.

Q. So what this shows is that the experiences with the rest of the world are not similar to the efficacy and complaint rates in the United States, correct?

A. Correct.

Q. And if you turn to Page 8, a global complaint review that Ethicon performed determined that the German experience regarding efficacy and complaints was not similar to the experiences in the United States, correct?

A. That's what they describe in this slide.

Q. And if you turn to Page 9, the analysis determined that the Australian experience was not

similar to the efficacy rates and complaints in the United States, correct?

A. That's what this states.

Q. And if you turn to Page 10, what they determined there was that the German and Australian experiences are not similar to the rest of the world and/or the United States, correct?

A. If you lump the rest of the world together as they did in this slide or the United States, that's what they showed in this slide.

Q. Do you have any reason to disagree with the findings on this page?

A. On this page?

Q. Yes.

A. This is what this page shows.

Q. My question was just a little bit different. Do you have any reason to disagree with the findings on this page?

A. There are other internal documents that say that the German and Australian experience was not unique as compared to what other doctors were experiencing around the world.

Q. And what data are you basing that on?

A. Those are internal documents.

Q. And you don't recall which ones those would be?

A. I don't recall specifically right now which documents they are.

Q. Do you recall if it was a formal analysis such as the presentation in front of you?

A. If I recall, it was a discussion between medical directors.

Q. And if you turn to Page 14, what this shows is the German and Australian experiences are, quote-unquote, different, correct?

A. That's what this slide states.

Q. And it also states that they are different than the USA?

A. That's what it states.

Q. It states that they are different than the rest of the world outside of the USA?

A. That's what this slide states.

Q. Now, what's important is that next bullet point, which states "Together the German" -- strike that. Paraphrasing here.

This next bullet point essentially states that the German and Australian TVT Secur sales were about 6.4 percent, but the complaints

from Germany and Australia accumulated to 91 percent of the total complaints regarding efficacy with TVT Secur?

A. That's what this slide states.

Q. And other than the internal e-mails that you have seen discussing something contrary to this, do you have any reason to dispute the findings on this page?

A. That's what this slide states.

Q. And you are not able to point me to the e-mails that would contradict the findings on this page right now, are you?

A. I don't have them at my fingertips, no.

Q. And if you turn to Page 15, part of the conclusion of the internal global complaint review was that aside from the outliers of Australia and Germany, there were no safety signals, correct?

A. That's what this slide states.

Q. And it also states that the mean failure rate for any TVT was approximately 15 to 20 percent?

A. That's what this slide states.

Q. And so what they noticed was that physicians were only complaining when this rate was

exceeded with TVT Secur, correct?

MR. WALDENBERGER: Objection to the form. You can answer.

A. This states physicians only, quote-unquote, complain when this rate exceeded.

Q. We are done with that document.

Doctor, are you critical of Ethicon for continuing to improve their -- strike that.

Are you critical of Ethicon for making attempts to improve their professional education materials even after TVT Secur was launched?

A. In what respect?

Q. Do you think it's a good thing that companies should try to continue to improve training and education materials?

MR. WALDENBERGER: You are not talking specifically regarding the TVT-S?

MR. ROSENBLATT: Not right now; just in general.

MR. WALDENBERGER: You can answer that.

A. Yes.

Q. With respect to the TVT Secur, do you agree that it was beneficial for Ethicon to

recognize that there was a problem with efficacy in certain locations and take steps necessary to improve the professional education?

MR. WALDENBERGER: Objection to the form. You can answer.

A. And what are you talking about as far as steps go? That's what I'm --

Q. Putting out additional professional education materials, making the steps clearer, coming out with key technique guides and various materials to supplement the IFU.

A. So you are talking about cookbooks, pearls and tips and tricks?

Q. Sure.

A. I describe that in my report.

Q. Right. My question is, are you critical of Ethicon for continuing to try to improve the professional education regarding the TVT Secur?

A. If these are critical steps, they should have been placed in the instructions for use and the instructions for use should have been updated to include these essentials for doing the procedure properly.

Q. And you recall when you were first

performing what is now the Burch, that procedure was done slightly differently, correct?

A. When I first started to perform the procedure?

Q. The MMK.

A. When I first started to perform the Burch procedure?

Q. Yes?

A. The same procedure that I do currently have.

Q. You haven't made any adjustments to your Burch procedure?

A. I've always done the Tanagho modification. Tanagho, T-a-n-a-g-h-o.

Q. And you would agree with me that not all surgeons who perform the Burch procedure do the Tanagho modification?

A. I can tell you what I do.

Q. So you don't know how other surgeons perform the Burch, correct?

A. I would say that when the Tanagho modification was described, it was adopted as the, you know, best way to perform the Burch procedure.

Q. And that was based on experience over

time, correct?

A. Correct.

Q. And that was based on comparing complication and efficacy rates over time, correct?

A. Correct.

Q. And after performing Burch procedure over time, some surgeons saw a benefit to performing the Tanagho modification, correct?

A. The Tanagho modification has benefits, yes.

Q. Doctor, have you reviewed the entire design history file for TVT Secur?

A. Yes.

Q. About how many pages was that, do you recall?

A. I don't recall specifically.

Q. Do you recall how many cadaver labs Ethicon performed on the TVT Secur?

A. I know that they performed a sheep study, the cadaver lab and the multi-centered trial that had five weeks of data at the time of launch.

Q. And you would agree with me that the mesh other than being laser cut is the same mesh in TVT Secur as it was in TVT retropubic?

A. Yes.

Q. Other than the studies that you mentioned a moment ago, are you aware of any other cadaver labs or testing that was done on TVT Secur prior to launch?

A. Specifically those were the three areas that I saw of studies.

Q. Do you agree that a benefit of laser-cut mesh in particular with the TVT Secur is that it has less potential to cause retention than TVT or TVT-O?

A. Can you repeat the question?

Q. Yes. Do you agree that one of the benefits of laser-cut mesh is that -- strike that.

Would you agree with me that one of the benefits of laser-cut mesh used in TVT Secur is that it has less potential to cause retention than TVT or TVT-O?

A. And am I assuming that the mesh used for the TVT or TVT-O is laser cut also?

Q. You tell me. Does that change your answer?

A. I'm not the one that's asking the question.

Q. Assume that TVT and TVT-O are mechanically cut.

A. Would the laser cut minimize the risk of retention?

Q. Yes.

A. Compared to TVT and TVT retropubic, TVT and TVT-O?

Q. Yes.

A. We are comparing apples and oranges.

MR. ROSENBLATT: Just give me one second. I will try to wrap up with this, Doctor.

MR. WALDENBERGER: Famous last words.

BY MR. ROSENBLATT:

Q. Would you agree that a reasonably prudent pelvic floor surgeon who was performing surgeries to treat stress urinary incontinence would stay current with the peer-reviewed medical literature?

A. Yes.

Q. And would you agree that that same reasonably prudent pelvic floor surgeon would base their clinical decisions on their medical training, their clinical experience, their review of

literature, their discussions with colleagues, their experience at seminars, professional society meetings and other education events?

MR. WALDENBERGER: You want to re-read that one? Is it compound?

THE WITNESS: I mean --

MR. ROSENBLATT: I'm trying to save some time, but I can break it down for you.

MR. WALDENBERGER: Why don't you break it down.

BY MR. ROSENBLATT:

Q. Doctor, would you agree that a reasonably prudent pelvic floor surgeon would be expected to make evidence-based decisions based on their medical training?

A. Yes.

Q. Based on their clinical experience?

A. Yes, in the hypothetical sense.

Q. Yes.

A. Okay.

Q. Based on their review of published medical literature?

A. That they have available, yes.

Q. Based on their discussions with mentors

and colleagues?

A. Assuming that they are having discussions with mentors and colleagues, yes.

Q. And based on their experience at professional society meetings and seminars?

A. Depending on their availability to go to professional meetings and seminars.

Q. And based on their involvement in professional education, events or continuing medical education events?

A. Based on what medical seminars and continuing medical education events that are available to them.

Q. And you would agree that a reasonably prudent pelvic floor surgeon would be aware of the potential risks associated with general surgery?

A. If they are a general surgeon.

Q. And you would agree that a reasonably prudent pelvic floor surgeon would be aware of the potential risk associated with all pelvic floor surgeries?

A. It depends on again their level of education, their level of experience. It's very difficult for me to say what all pelvic surgeons

know, what all pelvic surgeons are exposed to, what all pelvic surgeons read.

Obviously I have been exposed to and read things that are probably not available to the average pelvic surgeon, but based on what their patient population is, their interest level, the information they're exposed to, then yes.

Q. Would you agree that a reasonably prudent pelvic floor surgeon performing incontinence procedures would be aware of the risks and complications associated with the Burch colposuspension procedure?

A. Again, depending on their level of training, their expertise, the patient population that they see, their training, yes.

Q. And would that same answer apply to synthetic midurethral slings?

A. Well, there are a variety of aspects of the synthetic midurethral slings that is intrinsic to the procedure and to the material itself, and so I am not -- I do not think that the average physician would know all of the aspects of the synthetic material itself, such as degradation, mesh contraction, the chronic foreign body reaction

and the implications of the chronic foreign body reaction, all the things that I described in my report.

Q. What are you basing that on?

A. What am I basing that on?

Q. Yes.

A. Having spent five years intensively researching and reading and reviewing not only the medical literature but internal documents, testimony from medical experts at Ethicon. I have been exposed to and have read and seen and probably know more than the average physician just because of the sheer volume of material that I have reviewed.

Q. But you don't know what the average physician does or doesn't know, do you?

MR. WALDENBERGER: Objection to form.

You can answer.

A. No, I do not.

Q. Would you agree with me, Doctor, that regardless of whether a synthetic midurethral sling is laser cut or mechanically cut, they can ultimately lead to the same complications?

A. By different mechanisms, yes.

MR. ROSENBLATT: Nothing further at this time.

MR. WALDENBERGER: No questions.

MR. LUNDQUIST: None for the MDL either.

THE REPORTER: Signature?

MR. WALDENBERGER: Read and sign, usual stips, read and sign.

MR. ROSENBLATT: And my understanding is that the de bene esse deposition will take place next Wednesday.

MR. WALDENBERGER: Correct.

MR. ROSENBLATT: Off the record.

(At 3:02 p.m. the deposition was concluded.)

CERTIFICATE OF CERTIFIED SHORTHAND REPORTER

I, PAULINE M. VARGO, a Certified Shorthand Reporter of the State of Illinois, C.S.R. No. 84-1573, do hereby certify:

That previous to the commencement of the examination of the witness, the witness was duly sworn to testify the whole truth concerning the matters herein;

That the foregoing deposition transcript was reported stenographically by me and thereafter reduced to typewriting under my personal direction;

That the reading and signing of said deposition was reserved by counsel for the respective parties and the witness;

That the foregoing constitutes a true record of the testimony given by said witness before this reporter;

That I am not a relative, employee, attorney or counsel, nor a relative or employee of such attorney or counsel for any of the parties hereto, nor interested directly or indirectly in the outcome of this action.

CERTIFIED TO THIS 5th DAY OF FEBRUARY, A.D., 2016.

_____

Pauline M. Vargo, RPR, CRR
Illinois Certified Shorthand
Reporter No. 84-1573

INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it. It will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

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ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

BRUCE ALAN ROSENZWEIG, M.D. DATE

Subscribed and sworn
to before me this
_____ day of _____, 20____.

My commission expires:_____

_____
Notary Public

LAWYER'S NOTES

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